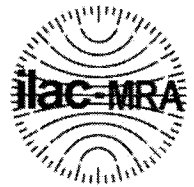


ET Docket No. 13-208

Perry Johnson Laboratory Accreditation, Inc.



Accepted / Filed

NOV 29 2017

Federal Communications Commission
Office of the Secretary

March 20, 2017

Mr. Julius Knapp, Chief Office of Engineering and Technology
Federal Communications Commission
445 12th Street SW
Washington, DC 20554

DOCKET FILE COPY ORIGINAL

Dear Mr. Julius Knapp:

We are currently requesting that our organization, Perry Johnson Laboratory Accreditation, Inc. (PJLA) be added to the recognized accreditation body list for the FCC OET Program. We are seeking approval to accredit within the United States for this program. As required within the recognition program for accreditation bodies, we have included several pieces of information and enclosures to support our credentials for this program.

We thank you for this opportunity and if you need any further information, please feel free to contact us directly.

Sincerely,

Tracy Szerszen, President/Operations Manager
tszerszen@pjlabs.com

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Summary of Perry Johnson Laboratory Accreditation Inc. (PJLA) FCC Application

Background/Experience

PJLA was established in 1999 as a private organization incorporated in the state of Michigan. We offer third-party accreditation services to various testing, calibration, reference material producer, field sampling measurement organizations and Inspection Bodies. Depending on the type of organization, accreditations are based on ISO/IEC 17025:2005, ISO Guide 34 or ISO/IEC 17020 and include additional sector specific, regulatory and government requirements as applicable. **(See IPL-2 PJLA Quality Manual, Enclosure 1).** We are recognized by the International Laboratory Accreditation Cooperation (ILAC) and by the Asia Pacific Laboratory Accreditation Cooperation (APLAC) as a competent accreditation body to operate an accreditation program for testing and calibration and RMP facilities **(See APLAC and ILAC Mutual Recognition Arrangements, Enclosure 2).** PJLA is evaluated every 4 years or sooner depending on the results of the APLAC MRA council **(See last two evaluation reports Enclosure 3-4).**

Additionally, we are also recognized as an acceptable accreditation body to perform industry specific or government accreditation programs. This includes the following: Consumer Product Safety Commission (Children's Products), EPA Energy Star, EPA National Lead Laboratory Accreditation Program (LQSR Version 3.) the Department of Defense Environmental Laboratory Accreditation Program (DoD ELAP) and TNI for the National Environmental Field Activities Program (NEFAP- TNI FSMO standard V1 and V2).

PJLA has a total of (885) accredited organizations and is continually growing within national and international markets.

Technical Details

PJLA will perform on-site assessments and routine surveillance visits to ensure the competency of each laboratory. Assessments will consist of a preliminary documentation review of the laboratory's technical documentation and procedures, and data within 30-days from the start of the on-site assessment.

An on-site assessment will be conducted upon a successful documentation review and will consist of a full system assessment of the laboratory to ISO/IEC 17025:2005 and specific FCC requirements. PJLA has a dedicated process for the assessment process and reporting process **(See Enclosure 5 SOP-1, Appendix G).** Assessors will be instructed to use the specific FCC checklist and provide assessment reports that consist of viable information in relation to the assessment and will be consistent with the requirements of ISO/IEC 17011:2004. Reports will include itemized findings, overview of the laboratory's compliance or non-compliance, PT performance and recommendations for approval or disapproval of the accreditation. All deficiencies and the final report will be provided to each laboratory at the end of each assessment during the debriefing meeting. Assessors will review corrective action submitted for any deficiencies detected within a sufficient period of time in order for a final certificate to be issued within 60 days from the corrective action submission date.

All certificates will include the laboratories' compliance with ISO/IEC 17025 and the appropriate FCC language as instructed in Table A of the FCC laboratory requirements. All certificates are issued for a 2 year period.

Assessor Qualification

Assessors are assigned based on their experience in the relevant field of test and technology as well as their knowledge with FCC expectation and regulations for the item under test. This experience encompasses direct work experience, technical education and on-going training. Assessors are expected to have completed full training of the latest version of the standard being assessed. Assessors have experience in relation to auditing skills and practices. Assessment teams will be established consisting of a lead assessor, technical assessor or technical expert as necessary. **(See attached Short Biographies/Resumes of Assessors, Enclosure 6)** *Note this listing of assessors are updated on annual basis and may not include all assessors within our program. *

PJLA will ensure all personnel including contracted staff sign conflict of interest agreements and confidentiality agreements protecting any information learned from services performed by PJLA **(See attached Template Forms Confidentiality LF-16, Conflict of Interest Forms (LF-36)- Enclosure 7-8).**

Experience

At this time, PJLA has no accredited FCC laboratories since this program requires laboratories to select an approved body in order to be on the FCC listing. However, we expect that we will gain more business within the next 12 months. At this time we have one applicant laboratory is seeking accreditation by our organization. Although, we may not have any laboratories accredited at this point for the FCC program we do have some laboratories that have similar scopes as those within the program **(See Reference List-Enclosure 9a-9b).**



Accreditation Procedure

PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to conformity assessments bodies.



Accreditation Procedure

1.0 INTRODUCTION

- 1.1 Perry Johnson Laboratory Accreditation, Inc. (PJLA) is a Michigan corporation wholly owned by Perry Lawrence Johnson ("Stockholder"). Mr. Johnson has no active management role in the operation of PJLA, and PJLA has no corporate relationship to Mr. Johnson's other business enterprises.
- 1.2 PJLA services include assessment and accreditation of conformity assessment body (CAB) systems to international, national, regulatory or governmental standards or program requirements.

2.0 SCOPE

- 2.1 This procedure covers the scope of the PJLA assessment and accreditation service. It conforms to ISO/IEC 17011: 2004 and other national and/or international standards as applicable. National, regulatory or government specific accreditation programs are outlined in appendices of this document. Accreditation criteria not covered in the appendices can be found in the body of this document. Note- In many cases, throughout this document, baseline ISO/IEC 17025:2005 program documents are referenced. Some of these documents belong to a series of documents for use in other accreditation programs (i.e. LF-1, LF-1 elap, etc.).

3.0 DEFINITIONS

- 3.1 **Accreditation Body (PJLA):** Authoritative Body that performs accreditation
- 3.2 **Accredited/Applicant Conformity Assessment Body (CAB):** A body that performs conformity assessment services that can be the object of accreditation
- 3.3 **Accreditation Certificate of Approval:** A formal document or set of documents, stating that accreditation has been granted for the defined scope
- 3.4 **Assessment:** Process undertaken by an accreditation body to assess the competence of the (CAB) based on particular standard(s) and/or normative documents and for a defined scope of accreditation



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- 3.5 **Assessor:** Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a (CAB).
- 3.6 **Preliminary Assessment (Preassessment):** An informal assessment carried out by PJLA to assess a (CAB) prior to the Initial Accreditation Assessment. The objective of the preassessment is to identify system gaps so that corrective actions can be implemented prior to the formal Accreditation Assessment.
- 3.7 **Accreditation/Reassessment:** Full System third-party attestation related to a (CAB) conveying formal demonstration of its competence to carry out specific conformity assessments tasks
- 3.8 **Surveillance Assessment:** Set of activities, except reassessment, to monitor the continued fulfillment by an accredited (CAB) of requirements for accreditation
- 3.9 **Accreditation Symbol:** A symbol issued by an accreditation body to be used by accredited (CAB) to indicate their accreditation status
- 3.10 **Registry:** Listing of accredited (CABs)

4.0 REQUEST FOR ACCREDITATION

- 4.1 The applicant (CAB) initiates the Accreditation Process via a written or verbal request for information. In response, PJLA provides the applicant with a Client Profile/Questionnaire (LF-1). PJLA will also supply them with additional PJLA accreditation system documentation/information as necessary.
- 4.2 The applicant completes the (LF-1), which provides PJLA with the initial information required to commence the accreditation process. This document elicits from the applicant the following details, among others:
 - a) Contact name (address, etc.)
 - b) Description of testing/calibration/RMP/FSMO/Inspection performed, including a description of activities performed at the organization's facility, customer locations, and in-house calibrations performed as applicable
 - c) Description of Equipment used
 - d) Description of Methods used
 - e) Description of premises of facility, number of employees, traveling employees and work shifts
 - f) Status of existing system



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- 4.3 If the (LF-1) is not complete, it will be rejected and the (CAB) will be contacted for more detail. No quotation will be generated without having enough information to determine the appropriate amount of time to spend at the facility, including information in regards to the (CAB) structure and scope.
- 4.4 PJLA makes its services available to all (CABs) whose requests are concurrent with PJLA's scope of activity. In the event the applicant requests accreditation services in unfamiliar areas, PJLA will utilize a technical expert to assist with the quoting process including the determination of: allocation of assessment days, assessor competency, and committee competency needs. If the technical resources cannot be formulated, then PJLA will reject the request for quotation.
- 4.5 On the basis of the information furnished by the applicant, PJLA provides a quotation to cover the cost of the accreditation and subsequent surveillance visits. The required number of assessment man-days is determined by examining the number and types of activities being performed at fixed locations and at customer locations, number of sites and number of technicians residing within the (CAB). At no such time will an accreditation assessment be quoted for less than 1.0 day on-site and .50 day off-site. The quotation may also include additional services such as preliminary assessments and on-site training activities. Applicants are informed that quotations received are based on the information as detailed in the application and is subject to change if inadequate or incomplete information was provided.
- 4.6 Should the applicant wish to proceed with accreditation, the applicant then signs, and returns a copy of the Agreement for Services bearing an original signature. The receipt by PJLA of this document is taken as an instruction to proceed in accordance with the agreement for services and associated procedures. At this stage, the applicant also provides PJLA with the following:
- a) Written confirmation of preferred dates for the preassessment (if applicable) and accreditation assessment;
 - b) Payment of the first installment per the Agreement for Services
- 4.7 Once the agreement is finalized a proposed scope for the assessment will be created based on the information retrieved from the application. This template will be submitted to the (CAB) prior to their assessment to confirm their scope and submitted to the lead assessor for verification and finalization during the on-site assessment.



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- 4.8 If the requirements for accreditation change at any time needing retroactive implementation, PJLA will ensure that the (CAB) is notified within a reasonable timeframe in order for the (CAB) to successfully complete implementation.
- 4.9 PJLA reserves the right to amend said Agreement for Services at any time if significant changes have occurred or unexpected circumstances take place with the applicant/accredited (CAB). This includes, but is not limited to: relocation, ownership change or merge, personnel changes, equipment, scope changes, complaints resulting in an on-site investigation, follow-up visits due to severe nonconformities, excessive corrective action review and follow-up activities. *It is the responsibility of the applicant/accredited (CAB) to inform PJLA of any significant changes that could impact their accreditation immediately.*

5.0 ASSESSMENT CONFIRMATION

- 5.1 Once the agreement for service is finalized PJLA will contact the applicant (CAB) to confirm the scope of accreditation and details of the organization as provided on the application. The scope of assessment will be developed upon confirmation of the assessment. Any questions or comments derived from the development of the scope will be submitted to the (CAB) for clarification. During the same time the (CAB) will discuss arrangements for the assessments (assessors, dates and off-site premises where activities of their scope are being performed as applicable), to ensure adequate time and an adequate schedule can be developed to perform the assessment. No Assessor will be assigned or permitted to conduct any assessments where they have participated in more than two (2) preliminary assessments of the accreditation client or in any way has given PJLA the impression that a conflict of interest could occur between the assessor and the (CAB). Assessors or any members of the team will have signed agreements with PJLA to avoid such conflict of interests with (CABs). The (CAB) will be clearly communicated in regards to the names of the assessor(s) by PJLA. The (CAB) has the right to object to any members of the assessment team assigned. PJLA appoints a qualified assessment team that includes members competent to assess the scope of the (CAB), including in-house calibration activities as applicable. If an assessment team cannot qualify for the scope of the (CAB) then a technical expert will be added to the team to provide the necessary technical expertise. Assessors and technical expertise will be evaluated against PJLA's Personnel Procedure (SOP-2) that includes guidelines for education, training and work experience requirements.



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- 5.2 (CABs) will be provided with a readiness review checklist to ensure they are well prepared for their assessment. This includes them to provide any updates to their original application such as their scope, organizational changes, and their fulfillment of internal audits, management review and proficiency testing performance. Additionally, documents to start the initial documentation review are also requested to be submitted within a timeline of at least 30 days prior to the on-site assessment. During this stage if any feedback is provided to PJLA indicating that they are not prepared for their assessment then the (CAB) will be notified that their assessment is recommended to be postponed.
- 5.3 (CABs) will be required to sign all assessment confirmation forms prior to each assessment. Postponement or cancellation of assessments obligates the (CAB) to pay cancellation fees as specified in (LF-3), Agreement for Services.

6.0 DOCUMENTATION REVIEW

- 6.1 At minimum PJLA will request baseline documents for the (CAB) to submit to initiate the documentation review. This includes documents such as: Quality Manual, performed and completed proficiency tests/inter lab comparisons as required per PJLA Policy PL-1, and measurement uncertainty budgets. * Note- Additional baseline documents may be requested depending on the accreditation program the (CAB) is applying for.* This will be communicated as necessary on specific Readiness Review Checklists. Once the documentation is received from the (CAB) the assessor will be notified and will begin the documentation review. Additional documents may be requested to be provided directly to the assessor(s) as necessary (i.e. SOPs, Work Instructions, Management Reviews, and Internal Audits). The lead assessor or team will complete their review and notify the (CAB) if any questions arise. The review will be documented on the LF-5a and placed in (CAB's) file. Assessors may identify nonconformities at this time that will be communicated to the (CAB) prior to or during the assessment. If the nonconformities are severe the assessor(s) will recommend that the assessment be postponed until the (CAB) is ready to proceed with accreditation. In such cases, the (CAB) will be communicated to in regards to the assessor(s) feedback and will be provided the opportunity to decide to 1) postpone the accreditation or 2) reduce their accreditation assessment to a preassessment. However, PJLA holds all rights to cancel assessments based on the (CAB's) undeveloped system. In any of the aforementioned situations, PJLA will place the (CAB's) application on "hold" status until receiving instructions from the applicant.



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- 6.2 Once the documentation review is completed and a recommendation is made to proceed with the on-site assessment, the lead assessor will develop an assessment plan. This will include specifics to the assessment including but not limited to: the scope of the (CAB), appropriate standard(s) and references, location(s), dates, start/end times, names of the assigned management representatives, assessor names with specific identified tasks, confidentiality statements and a listing to whom their final report will be distributed to. (CABs) will have the opportunity to review the assessment plan at least 14-days prior to the assessment and communicated with the lead assessor of any recommended changes. PJLA headquarters will also retrieve a copy of the plan to review and approve within a similar timeframe.

7.0 ON-SITE ASSESSMENT CRITERIA

- 7.1 Assessments are carried out in accordance to ISO 17011:2004 and consist of the following:
- a) An Opening Meeting is conducted with the (CAB's) management to confirm the scope and purpose of the assessment, review the assessment plan, reporting procedures and criteria for accreditation, introduce the assessment team and to confirm all relevant details for the assessment. The assessment team will also request that the (CAB) provides them any details in regards to proprietary information within their organization. They will explain the levels of possible nonconformities and observations that may or may not be detected during the visit. All members available at the opening meeting will also be required to sign an attendance sheet as evidence of their participation.
 - b) Detailed examination of the (CAB) itself, via personnel assessment, document review, and interviews of personnel. The assessment is conducted at all locations where key activities are performed. Activities performed at field sites controlled by the (CAB) are witnessed when as available and as scheduled between PJLA and the (CAB). * An appropriate number of staff is interviewed to ensure the competency of the (CAB) to perform activities covered by its desired scope, including staff performing in-house calibrations that affect the traceability of calibrations and/or test results. The (CAB's) methods for performing their scope are assessed that includes: technical competency, environmental conditions, equipment, traceability, reporting of the results, measurement uncertainty, records and method validation. The (CAB) is obligated to assist the assessment team by ensuring that all facilities related to the scope of accreditation are accessible and that an appropriate number of staff members are made available to interview. Members of the (CAB) should



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participate with the assessment team by clearly communicating with them on their processes and have the ability to promptly provide supporting documentation or records for areas being assessed. Any delays by the (CAB) and its staff may cause a delay in the entire accreditation or specific applied areas of the scope.

During the time of the on-site examination assessors will clearly communicate any nonconformities or observation detected to the (CAB) representative. This includes the following:

Major: A total absence of a required system element, or a series of minor nonconformities which, taken together, indicate a total breakdown of a required system element.

Minor: A single lapse in discipline or control.

Observation: In addition to major and minor nonconformities, an "observation" is another class of assessment finding. While not strictly a "nonconformance", a finding classified as an observation indicates that, in the opinion of the assessor, clarification or investigation is warranted to ensure the overall effectiveness of the system being assessed (Corrective action is not mandatory for observations).

If for any reason the assessment team is having difficulty identify whether a certain circumstance is or is not meeting the intent of the standard or PJLA policy then they may contact PJLA headquarters for clarification.

- c) A Closing meeting is conducted upon completion of the assessment. This includes a discussion of the (CAB's) performance against the standard being assessed and any nonconformities or observation detected. The (CAB) will be provided a copy of all nonconformities and observations as well as a detailed report to follow along with the discussion. A final recommendation to proceed or/not will be announced during this time. The assessment team will inform the (CAB) of the timelines required for corrective action responses as applicable. The (CAB) will be informed of PJLA's Appeal and Dispute Procedure (SOP-10) in the case nonconformities cannot be agreed upon. A final review of the scope will be reviewed and approved between the assessors and the (CAB) prior to the end of the meeting. Additionally, a witness schedule of the (CABs) scope of activities will be agreed upon between the lead assessor and the (CAB) to ensure all assessment activities are witnessed over a 6 year period. This will be documented on the LF-21 supplement form and included in each assessment package. A discussion will take place in regards to the final steps of the accreditation process including: details for corrective action submission, final accreditation decision process by the executive committee and final certificate submission. All members



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involved with the closing meeting will be asked to sign an attendance sheet as evidence of their participation. Nonconformities cited during the visit will as be required to be signed by the (CAB's) management representative as indication of their acceptance of the finding(s).

8.0 POST ASSESSMENT ACTIVITIES/CORRECTIVE ACTION SUBMISSION

- 8.1 (CABs) are required to submit appropriate corrective action responses for all nonconformities with sufficient objective evidence of closure. Corrective action responses should provide the assessment team confidence that the nonconformity has been corrected and contained. Objective evidence for statements or activities completed due to corrective action taken should coincide with the nonconformity and should be clearly identifiable to the assessment team. Failure to do so could cause a delay in the corrective action review process or a possible rejection for unacceptable corrective action. (CABs) can submit corrective action responses on the provided PJLA nonconformance report (LF-8) or supply their own as long as the content required is equivalent. (CABs) should avoid responses such as "see attached". This is not considered an appropriate corrective action response and will be rejected.
- 8.2 (CABs) have 60-days from the last day of the assessment to submit corrective action. Depending on the severity of the nonconformity this timeline may be adjusted or a follow-up visit to completely verify the effectiveness of the corrective action may be recommended. *Note some programs may require different timelines. In this case, these will be provided to the (CAB) during the closing meeting.* Failure to submit corrective action on-time or sufficiently may cause the accreditation to be voided requiring the (CAB) to re-apply or conduct a follow-up visit or suspension of a current accreditation. Multiple reviews of corrective action submissions are strongly discouraged and may cause PJLA to amend (CABs) agreements to include additional off-site time for the assessment team to complete the review.
- 8.4 In addition to corrective actions to nonconformities, the applicant (CAB) is also obligated to take corrective actions in response to complaints received, and to record the actions taken and their effectiveness.

9.0 FINAL ACCREDITATION DECISION

- 9.1 Upon completion and resolution of the assessment material including acceptable corrective action, the lead assessor makes a final recommendation to grant or deny the accreditation. Once the accreditation



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is recommended by the lead assessor the assessment material will be reviewed by PJLA headquarter staff for completion and submitted to the final decision making committee the Executive Committee. The Executive Committee is the final decision maker for the accreditation that grant or denies accreditation without undue delay. Members of the PJLA Executive Committee are independent parties from the assessment team that have no conflict of interest with the (CAB). Members are selected based on their fields of expertise aligning with the scope accreditation of the (CAB). More than one Executive Committee Member or Technical Reviewer may be selected to complete the final review. The final review consists of a complete assessment package review that should provide executive committee members confidence that the (CAB) is fully complying with the standard assessed and PJLA policies and have adequately responded to all non-conformities alleviating any doubt that the fulfillment of the requirements have been met. The Executive Committee may reject the assessment and request additional information at its discretion. In this case, the President/Operations Manager and/or Technical Program Manager(s) will instruct the lead assessor to retrieve more information from the laboratory or the laboratory may be communicated directly from PJLA headquarters. (CABs) have the opportunity to respond to any rejections or comments made by the Executive Committee. If the accreditation cannot be recommended by the lead assessor or the Executive Committee, then PJLA will communicate this to the (CAB). The (CAB) will either be required to completely reapply for accreditation or perform an extensive follow-up visit.

10.0 CERTIFICATE OF ACCREDITATION

- 10.1 Should the Executive Committee grant accreditation, PJLA issues a Certificate of Accreditation. Certificates are developed based on the final scope received from the assessment team. Once developed a draft is reviewed by a designated technical reviewer for adequacy against PJLA policies for certificates of accreditation. Any questions or comments derived from this review will be provided to the (CAB) or assessor for clarification. All certificates will be provided to the (CAB) for a final approval prior to release.
- 10.2 Certificates contain an initial accreditation date, an issue date (based on the date of the executive committee decision) and an expiration date and unique accreditation number and certificate number. The accreditation number remains the same for the life of the (CAB) as the certificate



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number is adjusted on an on-going basis. Revision dates are also issued as necessary. In some case, based on (CAB) preference the issue date may be later than the executive committee date. This is acceptable as long as the date is not before the approval date. The contents of the scope of accreditation include a scope statement from the (CAB) or a general scope field, based on the preference of the (CAB). A supplement is connected to each certificate that contains the items or activities the (CAB) is accredited for including an indication of activities being performed on-site at customer locations. The appropriate standard is indicated along with disclaimers to assist represent the entirety of the accreditation (i.e. CMC statements, remote/corporate scheme location references (some corporate certificates may include multiple certificate numbers (i.e. L12-006-1, L12-006-2), off-site activities references, etc.) (CABs) are required to approve their certificate draft. The PJLA symbol is provided on each certificate and the ILAC MRA mark for which PJLA has obtained recognition for. *Note some certificates are issued based on a separate accreditation cycle. The amount of these types of certificates is very minimal, but still remains valid until expiration. Effective April 1, 2011 this criteria has been relinquished and all (CABs) will be placed on a 2-year accreditation cycle.*

- 10.3 Once accreditation certificates are accepted by the (CAB) then a final certificate will be provided to the (CAB) via email in a non-editable format, hardcopy via mail and also posted on the PJLA website. Additionally, each (CAB) will be provided with a copy of the PJLA Accreditation Symbol Procedure (SOP-3) with the necessary artwork to promote their accreditation. Additionally, they will be informed about the use of the ILAC MRA mark that can be used along with the PJLA symbol. All (CABs) must adhere to the instructions outlined in (SOP-3) as outlined in their agreement for services. This includes requirements for the use of the accreditation symbols, the ILAC Mark and accreditation language. Assessors will review (CAB's) utilization of the accreditation symbol during on-site assessments and have full authority to document non-conformities for improper utilization. PJLA headquarters also has full authority to initiate a nonconformance against (SOP-3) if any misuse is found.

11.0 MULTIPLE SITE ACCREDITATION:

- 11.1 Where a (CAB) is operating through a number of remote locations or facilities, they may choose to pursue accreditation of all locations under a single accreditation if all of the following conditions exist:



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- a) The (CAB) has a similar quality management system that is implemented across all facilities
- b) The (CAB) defines a tiered management structure defining ultimate authority of the entire accreditation
- c) The (CAB) can attest that routine internal audits and management reviews encompass each facility and that they are reviewed by the designated management holding the ultimate authority over the entire accreditation. Note-records shall be made available to PJLA for all site internal audit or management review activities as requested.
- d) The authoritative site of the accreditation should be able to demonstrate their oversight of the following :
 - i) Policy Formulation
 - ii) Process and/or procedure development
 - iii) Contract review
 - iv) Approval and decision making on the results of conformity assessments
 - v) Management review;
 - vi) Internal audit planning and evaluation of the results
 - vii) Evaluation of corrective actions

11.2 On-site visits are conducted at all premises during the initial accreditation where activities are covered on the scope of accreditation and where the above key activities are performed. Upon accreditation all sites supporting the scope of accreditation or ones that meet the above key activities will be assessed on a routine basis throughout the accreditation cycle. In all cases, the designated authoritative location will be assessed annually and support sites/remote facilities will be sampled throughout the accreditation cycle. It is a practice that we complete a full system assessment of all facilities identified in the scope of accreditation over a two-year period. However, depending on the scope of activities being conducted at each location the schedule of assessments may be extended out to a 4-year period. A sampling schedule will be developed during initial contract stage and modified as appropriate based on feedback from the assessment team, or when an increase or decrease of sites or structural change occur.

12.0 MAINTENANCE OF ACCREDITATION

Surveillance Assessments

- 12.1 The continued fulfillment of accreditation requirements is maintained by conducting regular surveillance assessments. Surveillance assessments occur on-site within 12-months from the initial accreditation assessment.
- 12.2 Surveillance assessments are conducted to ensure compliance with accreditation requirements and are typically less comprehensive than



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accreditation assessments. At a minimum, the following aspects will be included during surveillance:

- a) Enquiries from PJLA to the (CAB) on aspects concerning the accreditation
- b) Declaration by the (CAB) with respect to their operation
- c) Documents and records, including updates from the quality manual
- d) (CAB's) performance (including through proficiency testing)
- e) Clauses of both the quality system and the scope of accreditation activities :
 - a. Internal audit and management review
 - b. Previous visit's findings
 - c. Outstanding corrective action
 - d. Performance in proficiency testing
 - e. Personnel changes and other changes
 - f. Changes in technical personnel or equipment
 - g. All PJLA policy requirements
 - h. Accreditation Symbol Utilization
 - i. Representative sampling of the accredited activities, covering all areas of competence

- 12.3 Since surveillance assessments are less comprehensive than accreditation or reaccreditation assessments, a lead assessor or a team of assessors may be selected for the assignment as long as they possess the skills to assess quality system areas and at least one of the technical areas. In this case, PJLA will inform the assessment team of which areas of the scope of accreditation is allowable for them to assess. PJLA along with the recommendation of the assessor(s) on the initial accreditation assessment will specify items that should be witnessed to ensure that over a full accreditation cycle a sufficient number of items on the scope of accreditation are witnessed.
- 12.4 Surveillance assessments although less comprehensive than full system assessments (i.e. AC, RA) still allow for nonconformities to be detected. (CABs) should follow the requirement as indicated in section 8.0 of this procedure.
- 12.5 Surveillance assessments are reviewed by PJLA technical staff to decide based on the assessor's recommendation to allow or deny the accreditation to be maintained. If major nonconformities, fundamental system changes



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or scope changes occur then the material will be passed onto the Executive Committee for a final recommendation.

- 12.6 After the initial accreditation cycle, PJLA reserves the right to amend the frequency of on-site visits. The interval between on-site assessments depends on the demonstrated competency of the (CAB) during the past accreditation cycle. This is developed from the recommendation of the lead assessor on previous visits, history of the (CAB) in regards to complaints, nonconformity trends, systems and/or technology changes. PJLA along with the lead assessor will make the final decision to excuse on-site surveillance visits. When on-site surveillance visits are reduced from the (CAB's) accreditation cycle, PJLA will require the (CAB) to demonstrate its maintenance of their accreditation through an off-site documentation review. This review consists of the following:

- 1) PT Data Review
- 2) Internal Audit Results
- 3) Management Review
- 4) Corrective Actions Taken
- 5) Review of changes occurred in the laboratory
- 6) Off-site Technical Review of at least one item on the scope of accreditation

Designated assessment time will be provided to an assigned assessor to complete this review. Non-conformities may be detected during these reviews requiring (CABs) to following the corrective action requirements as indicated in section 8.0 of this procedure. (CABs) will be provided with an assessment schedule from PJLA that includes the date and assessor conducting the review and the items required to be submitted. CABs will receive a final report from the assessor based on the review of the above items. PJLA staff will review the report to ensure the accreditation can be sustained. In the case severe issues arise during these reviews; PJLA has the right to request on-site visits to occur.

Proficiency Testing Maintenance

- 12.7 In effort to ensure all (CABs) meet the PJLA Proficiency Testing Requirements (PL-1), (CABs) are required to develop a 4- year Proficiency Testing Plan. This plan will be evaluated during on-site assessments. Any deviations from the specified requirements for PT will be evaluated PJLA headquarters and communicated to the assessment team (i.e. use of other means of PT such as intra laboratory comparisons or repeatability). Any changes to the 4 year PT plan should be communicated to the PJLA assessment team.



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Special Circumstance Assessments

- 12.8 PJLA reserves the right to conduct assessments during the course of the accreditation period when it is determined that the (CAB's) system may be or could potentially be at harm resulting in noncompliance with the standard. Situations such as the following may impose a special visit:
- a) Complaints from customers that are directed to the (CAB's) competency and results
 - b) Significant changes to the organization (i.e. ownership, management, address, technology/equipment change etc.)
- 12.9 If the changes do not directly affect the (CAB's) scope of accreditation results then it may be determined that a special assessment is not necessary and the changes will be reviewed during the regular assessment period.
- 12.10 If the (CAB) contemplates major changes it must notify PJLA

13.0 REASSESSMENT

- 13.1 At the end of the (CAB's) accreditation cycle, PJLA conducts a complete reassessment, similar to the initial accreditation assessment and its processes. Such assessments take into account PJLA's relationship with accredited (CAB) during the accreditation period as well as customer complaints and experience gained during previous assessments.
- 13.2 (CABs) are required to complete a reassessment assessment within 2 years from their last full system assessment. Some (CABs) requiring an expiration date will be scheduled at least 60-90 days prior to this date to avoid a lapse in accreditation. In the case the (CAB) runs over its expiration the President/Operations Manager will grant an extension. An extension of the certificate will granted depending on the circumstance.
- 13.3 Once the reassessment is submitted to headquarters for review the Accreditation Program Manager will conduct an entire Accreditation Cycle review of the accredited laboratory. This will consist of a full analysis of: the number of findings written throughout the cycle (2-3 years of assessment data), the nature of the findings and comments notated on the assessment report. If the Accreditation Program Manager finds that there is evidence that the assessor is over familiar with the laboratory's system, then the Accreditation Program Manager may discuss this issue with the President/Operations Manager. A decision will be made to change the assessor on the next accreditation cycle of the laboratory. However, during anytime in the accreditation cycle, PJLA may change assessors to ensure that assessments continue to be value-added, regardless of the results of the accreditation cycle review.



Accreditation Procedure

14.0 SCOPE EXPANSION

- 14.1 If a (CAB) requests to expand their scope of accreditation then they must complete an application for accreditation. PJLA will review the application and provide a quotation for the assessment time required to extend the scope of accreditation. Scope expansion may be conducted during any type of routine assessment or alone. Some scope expansions depending on the nature may be conducted off-site (i.e. expansions that include items that have already been witnessed and utilize the same equipment/technology).
- 14.2 Assessors will be selected as appropriate for all scope expansions. Special instructions will be given to the assessment team in regards to the areas to be assessed. At minimum the assessor will review the desired scope of accreditation to be extended against the applicable technical areas of the standard accredited to and any applicable quality management area that was impacted by the scope expansion. Non-conformities may be documented during scope extension assessments requiring (CABS) to comply with section 8.0 of this procedure in regards to corrective action response requirements. All scope expansions will be reviewed by the PJLA Executive Committee for a decision to grant/deny the additional scope items.

15.0 SUSPENSION, WITHDRAWAL, REDUCTION OR CANCELLATION OF ACCREDITATION

- 15.1 PJLA reserves the right to suspend, withdraw, reduce or cancel accreditation at any time during a (CAB's) accreditation period, in accordance with PJLA procedure SOP-11.
- 15.2 Generally, such actions are considered in the following instances:
- a) (CAB) fails to complete corrective actions during the agreed timeframe
 - b) (CAB) persistently fails to conform to Standard and/or PJLA Policies
 - c) (CAB), in PJLA's judgment, misuses PJLA's Accreditation Symbol, Certificate of Accreditation, or Accreditation language as outlined in SOP-3
 - d) (CAB) becomes delinquent in its financial obligations to PJLA
 - e) (CAB) becomes subject to bankruptcy laws or makes any arrangements or composition with its creditors; enters into liquidation, whether compulsory or voluntary; and/or appoints, or has appointed on its behalf, a receiver;
 - f) (CAB) is convicted of an offense tending to discredit the facility's reputation and goodwill



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- g) (CAB) commits acts that, in PJLA's sole judgment, impugn PJLA's goodwill, valuable name and reputation

15.3 PJLA reserves the right to publicize any actions it may take with respect to withdrawal, cancellation, reduction or suspension of an applicant (CAB's) accreditation.

15.4 PJLA will also cancel accreditation upon the formal written request of applicant (CAB).

15.5 PJLA may take legal action for wrongful actions specified in 15.2.

16.0 DISPUTES AND APPEALS

16.1 The (CAB) or any interested party may dispute or appeal the decisions of PJLA with respect to:

- a) Refusal to accept an applicant (CAB's) application for accreditation
- b) Failure to confer accreditation
- c) Suspension, withdrawal, reduction or cancellation of accreditation
- d) Refusal to extend an applicant (CAB's) Scope of Accreditation
- e) An appeal by a third party against PJLA's decision to grant accreditation
- f) Assignment of assessment team
- g) Nonconformities written by the assessment team
- h) or any other issue relevant to the accreditation process

16.2 (CABS) have access to the Dispute and Appeal Procedure (SOP-10) via PJLA website.

17.0 CONFIDENTIALITY

17.1 Except where required by law or statute, PJLA treats as confidential any information that comes into its possession in the course of the accreditation of the (CAB). PJLA, including all assessors, administrative staff, Executive Committee, Technical Committee and any other employee or contractor, promises not to disclose such information to any third party without prior written consent of the (CAB), except when required by law or statute. In the event that disclosure of such information is required by law or statute, PJLA will disclose the information as required and inform the (CAB) of such disclosure in writing in a timely fashion.



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Confidentiality Agreements will be signed and retained as evidence of agreement to the requirement of nondisclosure of confidential information



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APPENDIX A: THE NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM

1.0 SCOPE/PURPOSE

The National Lead Laboratory Accreditation Program (NLLAP) is an accreditation program designed to assess the competency and capability of (CABs) to analyze lead in matrices of paint chips, dust and or/soil according to the NLLAP and PJLA criteria.

This appendix includes the process for which PJLA carries out its accreditations in accordance with the NLLAP. This also includes specific requirements of applicant and accredited (CABs) wishing to obtain and maintain an accreditation to the NLLAP. This appendix only includes NLLAP program specific requirements, which are not found in the body of this document. Criteria outlined in the body of this document will be carried out by PJLA and enforced by PJLA to its (CABs) above these requirements as necessary.

2.0 REFERENCES

- 2.1 National Lead Laboratory Accreditation Program (NLLAP) Memorandum of Understanding
- 2.2 Laboratory Quality Systems Requirements (LQSR) Version 3.0, July 05, 2007.

3.0 DEFINITIONS

Accreditation-A formal recognition that (CAB) is competent to perform analyses of lead in paint chips, dust and or soil samples associated with the evaluation and control of lead-based hazards. Competence will be based on successful performance in both proficiency testing program and systems audit (inclusive of an on-site assessment) by programs/organizations recognized by NLLAP.

Assessor- One who performs systematic evaluation of a (CAB) on behalf of an accreditation organization.

Environmental Lead Proficiency Analytical Testing Program (ELPAT Program)-The proficiency testing program recognized by the NLLAP. * Participation on a quarterly basis in this program is mandatory for all (CABs) seeking accreditation by an NLLAP recognized accrediting organization.

EPA National Lead Laboratory Accreditation Program (NLAAP) - A voluntary (CAB) accreditation program with EPA OPPT oversight, which recognizes private sector and public accreditation organizations capable of performing adequate (CAB) assessments as part of their accreditation program of (CABs) requesting accreditation for their analysis of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards. (CABs) accredited by an NLLAP recognized accrediting organization will be recognized by EPA under NLLAP.

CAB-A facility that is requesting accreditation for the analyses of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards.



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(CAB) Accreditation Organization (accreditation organization)-An organization which seeks recognition from the EPA NLLAP as being capable of performing adequate (CAB) assessments for (CABs) requesting accreditation for the analysis of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards. (i.e. PJLA)

4.0 SUBSTANCE OF THE AGREEMENT

PJLA is recognized by the ILAC and APLAC MRAs as operating to ISO/IEC 17011 the successor document to ISO Guide 58. This guide is now obsolete and not used by the regional or international recognition bodies.

4.1 MANUAL/ORGANIZATION

PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for (CABs) seeking accreditation under the NLLAP program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of a (CAB's) accreditation status based on the (CAB's) failure to meet requirements of the program on an ongoing basis or at the (CAB's) request. PJLA will notify the EPA NLLAP in writing within five (5) working days of such actions.

PJLA will also notify the EPA/OPPT within 30 days after deciding on implementing major, substantive changes in its policies or management which could affect the EPA NLLAP program.

4.2 TRAINING AND QUALIFICATION

PJLA maintains a training, qualification and on-going continuing education program for assessors based on the EPA curriculum guidance document "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs- Revision 1.0" (EPA document No. 747-R-92-005). New and experienced assessors are required to meet the requirements contained in this document. Should the need arise to use training based on its own or other curricula, then these curricula will be submitted in advance to the EPA for review and approval. PJLA may, at its option, utilize the training of another accrediting organization. However, that accrediting organization must also be recognized under the EPA NLLAP.

4.3 ASSESSMENTS AND DOCUMENTATION

PJLA will perform on-site assessments of (CAB's) quality systems to include their general ISO/IEC 17025 requirements, the LQSR, and the specifics of the EPA NLLAP program. These will, at minimum, meet the requirements of the then current EPA NLLAP LQSR. Each assessment will include the completion of a checklist that follows the example of that in the "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations for Assessor Training Programs- Revision 1.0" or one that gives equivalent coverage of the example current to the requirements of the EPA NLLAP program. The



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checklist and other pertinent documentation will be kept for 10 years or otherwise instructed by the EPA NLLAP program (see 4.7 below).

4.4 PROFICIENCY TESTING (ACCREDITATION PROCESS)

PJLA requires all (CABs) applying or maintaining accreditation under the NLLAP to participate in the American Industrial Hygiene Association (AIHA) Environmental Lead Proficiency Testing Program (ELPAT) program on a quarterly basis. All (CABs) applying for accreditation and maintaining accreditation must perform such proficiency testing successfully and be rated "proficient" or "P" by the National Institute for Occupational Safety and Health (NIOSH) in their participation in the ELPAT program. PJLA will work with NIOSH and the (CAB) to secure the ELPAT data on an ongoing basis for the ELPAT program.

4.5 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

PJLA currently accredits (CABs) for a two-year accreditation cycle, supplemented with yearly surveillance assessments. While no change in this interval is anticipated, for the EPA NLLAP program, it will not exceed three years. Initial Accreditation and reassessments involve the off-site review of documentation and performance information and an on-site assessment that addressed all elements of ISO/IEC 17025 and the EPA NLLAP program.

4.6 NOTIFICATION (CERTIFICATE PROCESS)

PJLA will notify designated contacts at the EPA NLLAP of all accreditation approvals to include the effective date of accreditation, the expiration date and the specific matrices for which the (CAB) holds accreditation as expressed in its scope statement or scope supplement. This notification will be made within forty-five (45) days of the date the accreditation is effective. PJLA will send EPA NLLAP a current list of all (CABs) accredited under the program at least one every three months at minimum.

4.7 RECORD RETENTION (RECORDS/COMPLAINTS)

PJLA currently retains records from three (3) to five (5) years (depending on the record), minimum. However, records for the EPA NLLAP program will be retained for at least ten (10) years minimum. These records will include all complaints received from customers and others about (CABs) accredited by PJLA in the EPA NLLAP program.

4.8 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

PJLA will not delegate (whole or in part) the responsibility of (CAB) assessments to another organization, which is not itself recognized under the EPA NLLAP. This will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.

4.9 SUBCONTRACTING OF (CAB) ACTIVITIES



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(CABs) accredited by PJLA under the EPA NLLAP program will not subcontract routine sample analyses as described under the scopes of their accreditation and for which they are recognized unless the subcontracted (CAB) is also recognized under the EPA NLLAP program for the same analyses. Other provisions of ISO/IEC 17025 regarding subcontracting will, of course, also be enforced.

4.10 PARTICIPATION AND MAINTENANCE OF RECOGNITION

PJLA will participate in meetings with the EPA as scheduled and announced, or at least once every two years subject to EPA scheduling, to help in the evaluation, maintenance and improvement of the EPA NLLAP.



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APPENDIX B: THE TNI NATIONAL ENVIRONMENTAL FIELD ACTIVITIES PROGRAM (NEFAP)

1.0 SCOPE/PURPOSE

The NELAC Institute (TNI) National Environmental Field Activities Program (NEFAP) is an accreditation program designed to assess the competency and capability of Field Sampling and Measurement Organizations (FSMOs).

This appendix includes the process for which PJLA carries out its accreditations in accordance with the NEFAP. This also includes specific requirements of applicant and accredited (CABs) wishing to obtain and maintain an accreditation to the NEFAP. This appendix only includes NEFAP program specific requirements, which are not found in the body of this document. Criteria outlined in the body of this document will be carried out by PJLA and enforced by PJLA to its (CABs) as well as these requirements as necessary.

2.0 REFERENCES

- 2.1 Field Sampling and Measurement Organization Sector Volume 1 General Requirements for Field Sampling and Measurement Organizations (FMSO-V1-2014)
- 2.2 Field Sampling and Measurement Organization Sector Volume 2 General Requirements for Accreditation Bodies Accrediting Field Sampling and Measurement Organizations, (FSMO-V2-2014)
- 2.3 International Standard ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, September 2004

3.0 DEFINITIONS

Accreditation-A formal recognition that (CAB) is competent to perform field sampling and measurement. Competence will be based on successful performance in both proficiency testing program and systems audit (inclusive of an on-site assessment) by programs/organizations recognized by NEFAP.

Assessor- One who performs systematic evaluation of a (CAB) on behalf of an accreditation organization.

Field - Any location outside where work is performed outside the legal entity's facility (i.e. laboratory).

Field Measurement - The quantitative determination of physical, chemical, biological or radiological properties of a matrix by measurements made in the field.

Field Sampling - The process of obtaining a representative portion of an environmental matrix suitable for laboratory or field measurement or analysis.

Finding - An assessment conclusion referenced to an accreditation standard and supported by objective evidence that identifies compliance with and/or a deviation from an accreditation standard requirement.



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FSMO: Field Sampling and Measurement Organization.

Laboratory Accreditation Organization (accreditation organization) - An organization which seeks recognition from the TNI NEFAP as being capable of performing adequate assessments for FSMOs requesting accreditation for a specific scope of activities and in compliance with the NEFAP standards.

Matrix - The substance within which a measurement is made or from which a separate sample is collected. The matrix includes the physical, chemical, biological or radiological characteristics of the substance which may interfere with the measurement of some desired characteristic of the substance.

Preservation - Physical or chemical treatment of a sample to prevent the gain or loss of target analytes before analysis; filtration, refrigeration and addition of chemical reagents are examples of preservation techniques.

Proficiency Testing (PT) - A means of evaluating an organization's performance under controlled conditions relative to a given set of criteria through analysis of unknown samples provided by a proficiency testing provider.

Proficiency Testing Provider (PTP) - Any private party or government entity accredited by a TNI recognized PTPA that meets the stringent criteria to produce and distribute TNI samples, evaluate study result against published performance criteria, and reports the results to FSMOs, ABS, and its PTPA.

Proficiency Testing Provider Accreditor (PTPA) - An organization with technical expertise, administrative capacity and financial resources sufficient to implement and operate a program of PTP evaluation and oversight that meets the responsibilities and requirements established by the TNI FSMO and TNI Standard.

Sampling - See (ISO/IEC 17025; 2005(E), Clause 5.7.1, NOTE 1):

4.0 SUBSTANCE OF THE AGREEMENT

PJLA is recognized by the ILAC and APLAC MRAs as operating to ISO/IEC 17011.

4.1 MANUAL/ORGANIZATION

PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for organizations seeking accreditation under the NEFAP program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of an organization's accreditation status based on the organization's failure to meet requirements of the program on an ongoing basis or at the organization's request.



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4.2 TRAINING AND QUALIFICATION

PJLA maintains a training, qualification and on-going continuing education program for assessors based on the requirements in the TNI document FSMO-V2-2014. New and experienced assessors are required to meet the requirements contained in this document. PJLA may, at its option, utilize the training of another accrediting organization. However, that accrediting organization must also be recognized under the TNI NEFAP. PJLA will also recognize appropriate training conducted by federal, state, or local entities, academic/educational institutions or qualified private organizations.

FSMO assessors will possess a Bachelor's degree (or higher) in a scientific/technical discipline or have equivalent experience in environmental sampling and measurement. To be qualified all assessors will have to participate in at least four on-site assessments under the supervision of a qualified assessor. Initially, assessors in the beginning of the program will not have to be witnessed or supervised if they have completed at least four other FSMO on-site assessments and have been determined to be proficient by PJLA.

All assessors shall complete a basic training course that addresses the requirements of FSMO-V2-2014 and pass a written test. They shall also complete or have on record completion of at least one technical discipline involving sampling, measurement technologies, or a combination in areas such as: air matrices, solids (soils, sediment, sludge and soils monitoring), water (surface, waste, drinking and ground water), biological samples (ex: whole animals, fish, shell fish, plant or animal tissue, and micro-organisms). Annual refresher training will be provided to address (for example): regulations; accreditation processes and procedures and requirements; records and documents; data analysis, reduction and reporting; sampling and measurement methods and techniques; and other topics to improve assessment and communication skills.

All qualifications and training will be documented in the assessor files.

4.3 ASSESSMENTS AND DOCUMENTATION

PJLA will perform on-site assessments of organizations' quality systems to include their general ISO/IEC 17025 requirements, the FSMO-V1-2014, and the specifics of the TNI NEFAP program. These will, at minimum, meet the requirements of the then current FSMO-V1-2014. Each assessment will include the completion of a checklist that follows the example of that provided by the TNI NEFAP program or one that gives equivalent coverage of the example current to the requirements of the TNI NEFAP program. The checklist and other pertinent documentation will be kept for 5 years or otherwise instructed by the TNI NEFAP program (see 4.7 below).

4.4 PROFICIENCY TESTING (ACCREDITATION PROCESS)

PJLA requires all (CABS) applying or maintaining accreditation under the TNI NEFAP to participate in applicable and available proficiency testing (PT) programs from an approved PT provider to each scope



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of accreditation sought. This PT program must comply with PJLA Policy PL-1 and other related program specific requirements. If appropriate PT programs are not applicable or available then proficiency can be demonstrated by a variety of means such as (but not limited to): internal quality control check samples or programs; studies to establish method detection limits, precision, accuracy, and demonstrations of capability; internal self-monitoring and audits of the field sampling or measurement activities; or inter-organization studies.

4.5 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

PJLA currently accredits (CABs) for a two-year accreditation cycle, supplemented with yearly on-site surveillance assessments. While no change in this interval is anticipated, for the TNI NEFAP program, it will not exceed the times and conditions allowed in ISO 17011. Accreditation and re-accreditation assessments involve the off-site review of documentation and performance information and an on-site assessment that address all elements of ISO/IEC 17025 and the TNI NEFAP program.

4.6 ANALYSIS OF FINDINGS AND REPORT

PJLA will follow its documented procedures in the conduct of the assessments, documentation of findings (non-conformities/observations), and on-site reports. PJLA assessors will be expected to leave the documentation of findings and the report with the organization at the conclusion of the closing meeting. Also, the lead assessor is expected to send this documentation to PJLA HQ within 14 days from the end of the assessment (with allowances for travel, weekends, etc.). For the TNI NEFAP program, the assessed organization will have thirty (30) days to respond to the non-conformities with either the corrective actions for the non-conformities or a corrective action plan. An extension of this time frame may be agreed to in certain circumstances. PJLA will respond to this plan in a timely manner (less than 30 days). Consistent with current PJLA requirements all non-conformities must be closed or resolved with correction and containment, root cause, implementation of corrective action, and objective evidence or an assessable plan with objective evidence of implementation of the plan within 60 days of the closing meeting. All non-conformities must be so resolved prior to recommending accreditation.

4.7 RECORD RETENTION (RECORDS/COMPLAINTS)

PJLA currently retains records from three (3) to five (5) years (depending on the record), minimum. However, records for the TNI NEFAP program will be retained for at least five (5) years minimum. These records will include all complaints received from customers and others about (CABs) accredited by PJLA in the TNI NEFAP program. Specific program requirements may supersede these retention periods, but only by increasing them.

4.8 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)



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PJLA will not delegate (whole or in part) the responsibility of (CAB) assessment to another organization, which is not itself recognized under the TNI NEFAP. This will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.

4.9 SUBCONTRACTING OF (CAB) ACTIVITIES

(CABs) accredited by PJLA under the TNI NEFAP program will not subcontract activities described under the scopes of their accreditation and for which they are recognized unless the subcontracted organization is also recognized under the TNI NEFAP program for the same activities. Other provisions of ISO/IEC 17025 regarding subcontracting will, of course, also be enforced.

4.10 PARTICIPATION AND MAINTENANCE OF RECOGNITION

PJLA will participate in meetings with the TNI NEFAP as scheduled and announced, to help in the evaluation, maintenance and improvement of the TNI NEFAP. PJLA will undergo periodic re-evaluation as an AB by the TNI NEFAP program as required.



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Appendix C: Reference Material Producer (ISO Guide 34)

4.0 SUBSTANCE OF THE AGREEMENT

PJLA is recognized by the ILAC and APLAC MRAs as operating to ISO/IEC 17011. The APLAC MRA recognizes PJLA for its RMP program. There is currently no ILAC MRA for RMP.

4.1 MANUAL/ORGANIZATION

PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for organizations seeking accreditation under the RMP program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of an organization's accreditation status based on the organization's failure to meet requirements of the program on an ongoing basis or at the organization's request.

4.2 TRAINING AND QUALIFICATION

PJLA maintains a training, qualification and on-going continuing education program for assessors based on the requirements in the APLAC TC 008 document. New and experienced assessors are required to meet the requirements contained in this document. PJLA may, at its option, utilize the training of other accrediting organizations. However, those accrediting organizations must also be recognized under the APLAC RMP program. PJLA will also recognize appropriate training conducted by federal, state, or local entities, academic/educational institutions or qualified private organizations if available and equivalent.

RMP assessors will possess a Bachelor's degree (or higher) in a scientific/technical discipline or have equivalent experience in testing and/or calibration, production/quality control, statistics, reference material production or distribution. To be qualified all assessors will have to participate in at least four on-site assessments under the supervision of a qualified assessor. Initially, assessors in the beginning of the program will not have to be witnessed or supervised if they have completed at least four other on-site assessments and have been determined to be proficient by PJLA.

All assessors shall complete a basic training course that addresses the requirements of ISO Guides 34, 31, and 35, and APLAC TC 008 (or successor documents) and pass a written test. They shall also complete or have on record completion of at least one technical discipline as described in the previous paragraph. Annual refresher training will be provided to address (for example): regulations; accreditation processes and procedures and requirements; records and documents; data analysis, reduction and reporting; sampling and measurement methods and techniques; and other topics to improve assessment and communication skills.

All qualifications and training will be documented in the assessor files.



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4.3 ASSESSMENTS AND DOCUMENTATION

PJLA will perform on-site assessments of organizations' quality systems to include their general ISO/IEC 17025 requirements, ISO Guide 34 and related documents, (or successor documents) and the specifics of the APLAC RMP program. These will, at minimum, address the requirements of the then current APLAC TC 008 (or successor document). Each assessment will include the completion of a checklist that follows the requirements of the APLAC RMP program. The completed checklist and other pertinent documentation will be kept per 4.7 below.

The basis for the assessment of the RMP will be ISO Guide 34 (or successor document). The applicability of ISO 17025 requirements is done on a case-by-case basis depending on the functions and activities the RMP performs. When the RMP performs measurement, calibration and testing activities, the requirements of ISO 17025 would apply. If the RMP (or a subcontractor) is accredited by APLAC and/or ILAC MRA for the activities performed, this will be sufficient evidence of technical competency. If the RMP is not accredited for such activities where the requirements of ISO 17025 would apply, PJLA will include the assessment for these activities against the requirements of ISO 17025 as well as those contained in ISO Guide 34 (or successor document).

For guidance regarding RMP, subcontractor roles and the applicability of ISO 17025 and ISO Guide 34 (or successor document) requirements refer to APLAC TC 008 section 2.5.

4.4 PROFICIENCY TESTING (ACCREDITATION PROCESS)

PJLA requires all (CABS) applying or maintaining accreditation under the PJLA RMP program to participate in applicable and available proficiency testing (PT) programs from an approved PT provider to each scope of accreditation sought. This PT program must comply with PJLA Policy PL-1 and other related program specific requirements such as ILAC P9 for the tests or calibrations performed. This requirement also extends to (CAB) subcontractors performing analytical testing activities in the characterization, determination of homogeneity or stability, shelf life, or ongoing monitoring of reference materials. This requirement holds true whether the subcontractor is accredited or unaccredited. If appropriate PT programs are not applicable or available then proficiency can be demonstrated by a variety of means such as (but not limited to): internal quality control check samples or programs; studies to establish method detection limits, precision, accuracy, and demonstrations of capability; internal self-monitoring and audits of the measurement activities; or inter-organization studies.

4.5 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

PJLA currently accredits (CABs) for a two-year accreditation cycle, supplemented with yearly on-site surveillance assessments. While no change in this interval is anticipated, for the PJLA RMP program, it will not exceed the times and conditions allowed in ISO 17011. Accreditation and re-accreditation assessments involve the off-site review of documentation and performance information and an on-site assessment that address all elements of ISO/IEC 17025 and the ILAC RMP program. This includes subcontractor locations where warranted.



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4.6 ANALYSIS OF FINDINGS AND REPORT

PJLA will follow its documented procedures in the conduct of the assessments, documentation of findings (non-conformities/observations), and on-site reports. PJLA assessors are expected to leave the documentation of findings and the report with the organization at the conclusion of the closing meeting. Also, the lead assessor is expected to send this documentation to PJLA HQ within 14 days of the end of the assessment (with allowances for travel, weekends, particular circumstances, etc.). Consistent with current PJLA requirements all non-conformities must be closed or resolved with correction and containment, root cause, implementation of corrective action, and objective evidence or an assessable plan with objective evidence of implementation of the plan within 60 days of the closing meeting. All non-conformities must be so resolved prior to recommending accreditation or extending reaccreditation.

4.7 RECORD RETENTION (RECORDS/COMPLAINTS)

PJLA currently retains records from three (3) to five (5) years (depending on the record), minimum. These records will include all complaints received from customers and others about (CABs) accredited by PJLA in the APLAC RMP program. Specific program requirements may supersede these retention periods, but only by increasing them.

4.8 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

PJLA will not delegate (whole or in part) the responsibility of (CAB) assessment to another organization, which is not itself recognized under the APLAC RMP program. This will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.

4.9 SUBCONTRACTING OF (CAB) ACTIVITIES

(CABs) accredited by PJLA under the APLAC program may subcontract activities described under the scopes of their accreditation and for which they are recognized consistent with APLAC TC 008. In accordance to the APLAC MRA they shall not subcontract out production planning, the assignment and decision of property values, determination of their uncertainties, authorization of property values, and the issuance of certificates. Other provisions of ISO/IEC 17025 regarding subcontracting will, of course, also be enforced in that the RMP would need to determine the competence of the subcontractor for the work performed and have records of the qualifications and evaluation of the subcontractor(s). PJLA will review how the RMP selects subcontractors particularly for critical activities where the subcontractor generates measurements for the characterization of property values, homogeneity, and stability.

An on-site assessment of the subcontractor by the RMP is not normally needed if the testing or calibration subcontractor is accredited to ISO 17025 for the specific test or calibration, and the degree of the review done by the RMP of the contract or arrangement with its subcontractor is appropriate and at a minimum includes a review of:

- a) the measurand required,



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- b) the test and/or calibration method(s) used,
- c) the required measurement uncertainty,
- d) metrological traceability,
- e) the reporting requirements,
- f) the performance of proficiency testing activities (where suitable and applicable)
- g) attention by the subcontractor to performing the work with the required technical thoroughness.

When the testing or calibration subcontractor is not accredited, the same issues should be addressed, but an on-site assessment by the RMP may be required with records available for review.

For guidance regarding subcontractor roles and the applicability of ISO 17025 and ISO Guide 34 (or successor document) requirements refer to APLAC TC 008 section 2 2.3 & 2.4.

4.10 CERTIFICATES OF ACCREDITATION

PJLA only issues certificates of accreditation upon the final approval of the Executive Committee. These certificates will contain the effective date and the scope of accreditation consistent with PJLA policies, work instructions and APLAC TC 008 (or successor document) .

Scopes for RMPs will contain:

- Company name, location and contact information
- Reference Material Categories per ILAC G12:2000 Appendix B (withdrawn) or ISO/TR 10989:2009(E) Section 6/Annex A (if so directed at a later date)
- Items, matrix, material, or products
- Specific constituents or properties
- Specification, standard, method or technique used
- Range of constituents or property values (if applicable)
- Reference Value Capability* (RVC)
- RM/CRM (or both)
- Responsible Organization Type (per APLAC TC 008 Table 1)

*Per APLAC TC008 sections 6.5 & 6.6 "For CRMs, the scope of accreditation shall be expressed in terms of a best Reference Value Capability which shall include the RMPs estimate of its least uncertainty of measurement (U_{CRM}) for each property value's range it reports. ... CRMs that are an identification value (such as species identification) or where the property value is an ordinal number (such as a color fastness chart) do not require an uncertainty of measurement to be stated in the scope of accreditation." Per section 6.3 "An accredited RMP is not permitted to report on a RM certificate an uncertainty of property value which is less than or better than that stated in its scope of accreditation." See sections 6.7 through 6.11 for additional information.

If an RMP does certain activities that are outside the scope of its accreditation, it shall not claim that it is accredited for producing the RM concerned, and cannot use an endorsed certificate/statement/report for



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such a RM.

A listing of all accredited RMP CABs will be published on the PJLA site to include the: CAB name, address, contact, phone number, scope of accreditation. Any changes to the CAB's status will be indicated on the PJLA website.

4.11 PARTICIPATION AND MAINTENANCE OF RECOGNITION

PJLA will participate in meetings with APLAC as scheduled and announced, to help in the evaluation, maintenance and improvement of the APLAC RMP program. PJLA will undergo periodic re-evaluation as an AB by the APLAC RMP program as required upon the granting of full recognition by APLAC. This may involve other interested parties as observers in the evaluation process.



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APPENDIX D: DEPARTMENT OF DEFENSE LABORATORY ACCREDITATION PROGRAM (DOD ELAP)

1.0 SCOPE/PURPOSE

The Department of Defense Laboratory Accreditation Program (DoD ELAP) is an accreditation program designed to assess the competency and capability of (CABs) to the DoD Quality System Manual (QSM) including any additional PJLA policies.

This appendix includes the process for which PJLA carries out its accreditations in accordance with the DoD Quality Systems Manual for Environmental Laboratories (DoD QSM) Version 5.0 and the Conditions and Criteria for DoD Environmental Laboratory Accreditation Program Recognition of Accreditation Bodies. This also includes specific requirements of applicant and accredited (CABs) wishing to obtain and maintain an accreditation to the DoD ELAP. This appendix only includes DoD ELAP program specific requirements, which are not found in the body of this document. Criteria outlined in the body of this document will be carried out by PJLA and enforced by PJLA to its (CABs) as well as these requirements as necessary.

2.0 REFERENCES

- 2.1 DoD Quality Systems Manual for Environmental Laboratories Version 5.0 (DoD QSM)
- 2.2 International Standard ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, September 2004
- 2.3 Conditions and Criteria for DoD Environmental Laboratory Accreditation Program Recognition of Accreditation Bodies
- 2.4 National Environmental Laboratory Accreditation Conference (NELAC) Chapter 5 Quality Systems Standard (2009)

3.0 SUBSTANCE OF THE AGREEMENT

- 3.1 PJLA is recognized by Department of Defense EDQW to accredit (CABs) to the DoD QSM by means of the continuation and good standing of the ILAC/APLAC international MRAs and adherence to the criteria and condition criteria set fourth by the DoD for this program.

4.0 MANUAL/ORGANIZATION

- 4.1 PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011. These and other related documents (including this one) state all of the requirements for (CABs) seeking accreditation under the DoD ELAP program. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of an organization's accreditation status based on the organization's failure to meet requirements of the program on an ongoing basis or at the organization's request.

5.0 TRAINING AND QUALIFICATION



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- 5.1 PJLA maintains a training, qualification and on-going continuing education program for assessors based on the requirements of ISO/IEC 1701:2004 and the conditions and criteria set fourth by the DoD for the administration of the DoD ELAP. New and experienced assessors are required to meet the requirements contained in this document. PJLA may, at its option, utilize the training of another accrediting organization. However, that accrediting organization must also be recognized under the DoD ELAP. PJLA will also recognize appropriate training conducted by federal, state, or local entities, academic/educational institutions or qualified private organizations.
- 5.2 DoD ELAP assessors will possess a Bachelor's degree (or higher) in a scientific/technical discipline or have equivalent experience in environmental analysis.
- 5.3 All assessors shall complete a basic training and work experience in accordance to PJLA Personnel Procedure (SOP-2) including basic ISO/IEC 17025:2005 training, NELAC Training and DoD QSM Training. Annual refresher training will be provided to address (for example): regulations; accreditation processes and procedures and requirements; records and documents; data analysis, reduction and reporting; and measurement methods and techniques; and other topics to improve assessment and communication skills. Curriculums for annual training will be provided to the EDQW for review and approval prior to execution.
- 5.4 All qualifications and training will be documented in the assessor files.

6.0 ASSESSMENTS AND DOCUMENTATION

- 6.1 PJLA will perform on-site assessments of (CABs) laboratory systems to include the latest version of the DoD QSM and PJLA Policy Requirements. Each assessment will include the completion of a checklist and supplemental documents that provide sufficient evidence that all applicable elements of the DoD QSM have been assessed. The EDQW will be notified immediately when an assessment is scheduled. PJLA will cooperate with the EDQW in all cases when (CABs) are selected to be witnessed. Prior to each assessment PJLA will require documentation to be submitted that includes: the quality manual, SOPs, PT listing/results/data packages, previous audit reports, LOD/LOQs, Laboratory Control Limits/Charts for Laboratory Control Sample for each method and a completed PJLA DoD ELAP checklist,

7.0 PROFICIENCY TESTING (ACCREDITATION PROCESS)

- 7.1 PJLA requires all (CABS) applying or maintaining accreditation under the DoD ELAP program to comply with PJLA Policy PL-1 and with the requirements of the DoD QSM. Applicant or accredited (CABS) shall ensure that all items on their scope of accreditation undergo a proficiency test at least every 6 months. These proficiency tests shall be conducted by competent providers as indicated in the DoD QSM or NELAC Chapter 5. In the case, third party providers are not available then the (CAB) must be able to demonstrate their adherence by utilizing other sources as outlined in PJLA Policy PL-1



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(i.e. inter lab comparison, intra lab comparison, repeatability studies). This must be approved by PJLA. (CABs) are responsible for informing PJLA of their PT performance. This is initiated by submitting PJLA a listing PT(s) performed including the analyte, method, matrix, timeframe for performance and results. PJLA will provide each CAB with a PT tracking sheet (LF-127) to initially enter their data prior to accreditation. PJLA expects that at least 18 months of data is recorded initially. On-going maintenance of the PT tracking sheet will be required to be completed and updated within 14 days of receiving results. Failure to adhere to this requirement will result in a nonconformity.

8.0 ACCREDITATION INTERVAL/CYCLE (ASSESSMENT PROCESS)

- 8.1 PJLA currently accredits (CABs) for a two-year accreditation cycle, supplemented with yearly surveillance assessments. Accreditation and re-accreditation assessments involve a full system assessment of the (CAB).

9.0 ANALYSIS OF FINDINGS AND REPORT

- 9.1 PJLA will follow its documented procedures in the conduct of the assessments, documentation of findings (non-conformities/observations), and on-site reports. PJLA assessors will be expected to leave the documentation of findings and the report with the organization at the conclusion of the closing meeting. Also, the lead assessor is expected to send this documentation to PJLA HQ within 14 days from the end of the assessment (with allowances for travel, weekends, etc.). Assessment reports will be submitted to the EDQW upon receipt. Consistent with current PJLA requirements all non-conformities must be closed or resolved with correction and containment, root cause, implementation of corrective action, and objective evidence or an assessable plan with objective evidence of implementation of the plan within 60 days of the closing meeting. All non-conformities must be so resolved prior to recommending accreditation. Additional assessment material such as: corrective action plans, full corrective action taken for nonconformities and AB feedback will be provided to the EDQW upon request.

10.0 RECORD RETENTION (RECORDS/COMPLAINTS)

- 10.1 DoD ELAP assessment material and pertinent recorder will be retained for at least five (5) years minimum. Specific program requirements may supersede these retention periods, but only by increasing them.

11.0 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

- 11.0 PJLA will not delegate (whole or in part) the responsibility of (CAB) assessment to another organization without the approval of the EDQW. This will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.



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12.0 SUBCONTRACTING OF (CAB) ACTIVITIES

- 12.1 (CABs) accredited by PJLA under the DoD ELAP program will not subcontract activities described under the scopes of their accreditation and for which they are recognized unless the subcontracted organization is also recognized under the DoD ELAP program for the same activities. Other provisions of ISO/IEC 17025 regarding subcontracting will, of course, also be enforced.

13.0 CONFIDENTIALITY

- 13.1 PJLA at all times will keep records including the results of each assessment confidential. (CABs) will be informed to whom the report will be distributed to including the EDQW.

14.0 CERTIFICATES OF ACCREDITATION

- 14.1 PJLA only issues certificates of accreditation upon the final approval of the Executive Committee. These certificates will contain the effective date, the scope of accreditation (matrices, method, technology, analyte). Information from the scope of accreditation will be prepared on a Denix load sheet and submitted to the EDQW for uploading. A listing of all accredited (CABs) will be published on the PJLA site to include the: CAB name, address, phone number, scope of accreditation. Any changes to the (CAB's) status will be indicated on the PJLA website and the EDQW will be notified within 5 business days of the change.

15.0 PARTICIPATION AND MAINTENANCE OF RECOGNITION

- 15.1 PJLA will comply at all times with the criteria and condition set forth by the DoD for the administration of this program. PJLA will participate in EDQW annual meetings and monthly conference calls as part of the continual improvements efforts for the DoD ELAP. PJLA will maintain continuation of international recognition by ILAC and APLAC for testing. The EDQW will be informed of PJLA's ILAC/APLAC evaluation schedule at least 6 months prior to the scheduled date to invite a member to participate and will be notified within 30 days of any changes to our signatory status. Reports resulting from the evaluation will be submitted to the EDQW for review within 30-days of receipt. PJLA will report any changes to EDQW of any major changes such as: legal, commercial, organizational or ownership status, organizational and management (i.e. key managerial staff), policies or procedures where appropriate, location change, personnel, facilities, working environment or other resources, where significant, authorized representative for the program or any other matters that could affect the integrity of the accreditation program.



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APPENDIX E: TNI -NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)- FOR NON-GOVERNMENTAL ACCREDITATION BODIES

1.0 SCOPE/PURPOSE

The NELAC Institute (TNI) National Environmental Laboratory Accreditation Program (NELAP) is an accreditation program designed to assess the competency and capability of environmental and drinking water laboratories. This standard(s) and/or criteria utilized for this program is the TNI Standard Volume 1 and 2 (2003) and/or (2009) the United States Environmental Protection Agency's (EPA) Manual for the Certification of Laboratory's Analyzing Drinking Water, Fifth Edition.

This appendix includes the process for which PJLA carries out its accreditations in accordance with the (NELAP). This also includes specific requirements of applicant and accredited (CABs) wishing to obtain accreditation to the NELAP. This appendix only includes NELAP program specific requirements, which are not found in the body of this document. Criteria outlined in the body of this document will be carried out by PJLA and enforced by PJLA to its (CABs) as well as these requirements as necessary.

2.0 REFERENCES

2.1 Management and Technical Requirements for Laboratories
Performing Environmental Analysis (TNI-EL-V1-2011)

2.2 General Requirements for Accreditation Bodies Accrediting Environmental Laboratories (TNI EL-V2-2011)

2.3 International Standard ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, September 2004

3.0 PJLA ROLES AND RESPONSIBILITIES TO TNI NELAC PROGRAM

PJLA is committed to ensuring timely TNI NELAP/ EPA-compliant laboratory assessment are conducted in a cost-effective manner, with the regulatory oversight required by law.

4.0 SUBSTANCE OF THE AGREEMENT

PJLA meets the criteria as outlined in requirements for TNI Non-Governmental Accrediting Body program in addition to the Management and Technical Requirements for Laboratories Performing Environmental Analysis (TNI-EL-V1-2011), the General Requirements for Accreditation Bodies Accrediting Environmental Laboratories (TNI EL-V2-2011) and International Standard ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, September 2004.



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4.1 MANUAL/ORGANIZATION

PJLA maintains a quality manual and standard operating procedures (SOPs) and work instructions to document its quality system to comply with ISO/IEC 17011 and TNI EL- V1 and V2. PJLA will follow its organization procedures as specified in these documents in the removal, suspension or withdrawal of an organization's accreditation status based on the organization's failure to meet requirements of the program on an ongoing basis or at the organization's request.

4.2 TRAINING AND QUALIFICATION

PJLA maintains a training, qualification and on-going continuing education program for assessors based on the requirements outlined in ISO 17011:2004, the TNI EL-V1 and V2 standards and the EPA Manual for the Certification of Laboratory's Analyzing Drinking Water, Fifth Edition Criteria. New and experienced assessors are required to meet the requirements contained in this document. PJLA will also recognize appropriate training conducted by federal, state, or local entities, academic/educational institutions or qualified private organizations.

- 4.2.1 Laboratory assessors shall hold at least a Bachelor's degree in a scientific discipline or have commensurate experience acquired by having performed verified assessments of environmental CABs. An assessor shall have completed and attained a passing score on the written examination of courses on assessing quality systems and all technical disciplines comprising a technology or combination of method and technology that the assessor will assess.

NOTE: Technical disciplines applicable to the environmental sector include microbiology, toxicity testing, inorganic non-metals, metals, organics, asbestos, radiochemistry, and field activities.

- 4.2.2 Assessors shall sign qualification statements attesting the assessors meet the education and training required above. PJLA shall provide these statements to CABs upon request.
- 4.2.3 Assessors shall have performed a minimum number of assessments under the supervision of an assessor whose competence has been qualified by PJLA. The qualified assessor shall observe the candidate assessor performing:
- a) at least one assessment, for those assessors that have previous documented experience performing environmental CAB assessments; or
 - b) at least two assessments, for those assessors that have no documented experience performing environmental CAB assessments.

NOTE: A qualified assessor may evaluate the ability of an assessor to perform unsupervised assessments by: direct observation, observing the assessor perform an assessment in its entirety; or by limited observation, observing the assessor performing parts of an assessment and allowing the assessor to conduct some parts of the assessment independently.



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- c) Supervised assessments will be documented on an LF-100 Evaluation form as outlined in SOP-2 PJLA Personnel Procedure).
- 4.2.4 Annual refresher training will be provided to address (for example): regulations; accreditation processes and procedures and requirements; records and documents; data analysis, reduction and reporting; sampling and measurement methods and techniques; and other topics to improve assessment and communication skills.
- 4.2.5 All qualifications and training will be documented in the assessor files.
- 4.3 STANDARDS OF PROFESSIONAL CONDUCT OF ASSESSORS**
- 4.3.1 Assessors and experts shall conform to professional and ethical standards of conduct. Assessors and experts shall:
- a) have no interests at play other than those of PJLA during the entire accreditation process;
 - b) act impartially and not give preferential treatment to any organization or individual;
 - c) provide equal treatment to all persons and organizations regardless of race, color, religion, sex, national origin, age, and disability;
 - d) not use their position for private gain;
 - e) not solicit or accept any gift or other item of monetary value from any CAB, CAB representative or any other affected individual or organization doing business with, or affected by, the actions of the assessor's employer or accreditation body;
 - f) not hold financial interests that conflict with the conscientious performance of their duties;
 - g) not engage in financial transactions using information gained through their positions as assessors to further any private interest;
 - h) not seek or negotiate employment or attempt to arrange contractual agreements with a CAB that would conflict with their duties and responsibilities as assessors;
 - i) not knowingly make unauthorized commitments or promises of any kind purporting to bind PJLA.
 - j) attempt to avoid any actions that could create the appearance that they are violating any of the standards of professional conduct outlined here above



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- 4.3.2 Assessors that become aware that the CAB may be in violation of an environmental law or regulation shall inform PJLA of the situation and provide documentary evidence for PJLA to take appropriate action.

4.4 ASSESSMENT DOCUMENTATION

- 4.4.1 PJLA will perform on-site assessments of organizations' quality system to include the general ISO/IEC 17025, TNI EL-V1 and EL-V2. Assessment material will include the following at minimum:

- a) Checklist covering the entire TNI EL-V1 Standard and other program specific requirements
- b) A preliminary and final assessment report
- c) Attendance Sheet with members participating in the opening and close of the assessment
- d) Nonconformity reports and evidence of closure
- e) Proficiency Testing Results
- f) Other data to support the assessment
- g) Appraisal Form

- 4.4.2 The assessment teams shall provide or make available the following types of documents before a scheduled announced on-site assessment or before the conclusion of the on-site portion of the CAB assessment:

- a) Assessment Confidentiality Notice: a document advising the CAB that it has the right to declare information gathered during an assessment as confidential business information according to procedures established by the accreditation body or to restrict access to information requested during an assessment when such information directly affects national security.

PJLA will utilize (SOP 10) Dispute and Appeal procedure for processing and evaluating claims made by CABs of confidential business information (CBI) referencing applicable laws and regulations.

- b) Checklists: any standard forms that the assessment team will use to evaluate conformance with the standard to document assessment findings.

- c) Assessment Appraisal Form: a document used by the accreditation body to obtain feedback from CABs about the adequacy and the effectiveness of the assessment process, including the performance of the assessment team.



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d) Notice of Announced Assessment: an appointment letter, electronic mail message or a published schedule informing the CAB about an upcoming assessment and identifying members of the assessment team with sufficient time to allow for potential objections from a CAB to members assigned to the assessment team.

4.5 ACCREDITATION INTERVAL/CYCLE

Assessments will be conducted annually consisting of an initial assessment, surveillance and a reassessment. All (CABS) shall be fully reassessed every two years. In certain circumstances reassessments can occur 6 months prior or after the reassessment due date. Routine assessments will be announced to (CABS) in accordance to this procedure. However, PJLA has the right to conduct assessments unannounced when necessary. Since these assessments are unannounced the CAB may object to the assessment team upon their arrival. PJLA will handle these situations as they arise and deem whether the CABs objection of an assessor or team is reasonable and reassign assessors as necessary. However, at no such time is an objection to conduct an unannounced assessment from the (CAB) acceptable.

4.6 ASSESSMENT PROCESS

4.6.1 Application Process

PJLA will review all applications received for NELAP and determine the appropriate amount of assessment time and qualified assessment teams. All cost estimates will be provided directly to the (CAB) for consideration within a reasonable number of contiguous working days.

4.6.2 Conduct Assessments

All assessments will be conducted in accordance to the specified standard (i.e. TNI EL V-1 (2003) (2009). Assessments will include the assessment of the standards in its entirety including the assessment of all Fields of Accreditation (Matrix-Method Analyte combinations) for which the CAB holds accreditation.

4.6.3 Assessment Reporting

An assessment report will be developed from the assessment team consisting of requirements as outlined in PJLA criteria and TNI EL-V2 criteria. Nonconformities shall be documented against the applicable standard requirement and as necessary against the adherence to accredited test method specifications. A preliminary assessment report including the determinations of potential findings shall be left at the closing meeting. A final assessment report will be issued within 30 days of the assessment once all findings are confirmed. No assessment reports will be released to the public until all reports and nonconformities have been finalized.



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4.6.4 Post Assessment Activities

(CABs) will be required to respond to nonconformities within 30 calendar days from the receipt of the final on-site report. Responses shall include a plan of correction (i.e., corrective action plan) for each nonconformity identified in the on-site assessment report.

4.7 GRANTING OR DENIAL OF ACCREDITATION

Upon final approval by the assessment team all assessment material will be reviewed by PJLA's Executive Committee. This committee is independent from the assessment team and impartial to the CAB's activities. Upon approval of the committee a certificate will be granted including an issue date, expiration date, test matrices, test methods, technology and applicable analytes. Certificates will be maintained on the PJLA website of accredited laboratories www.pjlab.com.

Denial of accreditation may occur for the following situations:

- a) failure to submit a completed application;
- b) failure to pay fees;
- c) failure of CAB staff to meet the personnel qualifications of education, training, and experience as required by the Standard;
- d) failure to successfully analyze and report proficiency testing samples as required;
- e) failure to respond to an assessment report from an on-site assessment with a corrective action report as required;
- f) failure to implement the corrective actions detailed in the corrective action report within the required time frame.
- g) failure to implement a quality system as defined in TNI Environmental Laboratory Sector Volume 1, Module 2 "Management and Technical Requirements for Laboratories Performing Environmental Analysis";
- h) failure to pass a required on-site assessment(s);
- i) misrepresentation of any fact pertinent to receiving or maintaining accreditation; and/or denial of entry during normal business hours for an on-site assessment.

No CAB's accreditation shall be denied without the right to due process.

4.8 SUSPENSION, WITHDRAWAL AND REDUCTION OF ACCREDITATION

PJLA has a policy for the Suspension, Withdrawal and Reduction of Accreditation (SOP-13), available on the PJLA website. In addition to this general policy CABs under this program will have the following requirements placed upon them in association to this process.



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Suspension shall not exceed six months or the period of accreditation, whichever is longer. Subject to applicable laws, regulations and due process requirements, PJLA may suspend, withdraw or reduce a CAB's accreditation if the CAB fails to meet the standards for accreditation. The CAB shall retain accreditation for the scope of accreditation, where it continues to meet the requirements of the Standard.

Reasons for suspension, withdrawal or reduction shall include but are not limited to:

- a) if PJLA finds, during the on-site assessment, that the public interest, safety or welfare imperatively requires emergency action;
- b) failure to complete proficiency testing studies as required;
- c) failure to notify PJLA of any changes in key accreditation criteria
- d) failure to maintain a Quality System as required;
- e) failure of the CAB to employ staff that meets qualifications for education, training and experience as required.
- f) Misrepresentation of any fact pertinent to receiving or maintaining accreditation;
- g) Denial of entry to PJLA's assessment team during normal business hours for the purpose of conducting an on-site assessment;
- h) Failure to pass an on-site assessment conducted by PJLA;
- i) Failure to complete responses or corrective actions from PJLA's assessment report.
- j) Failure to pay fees

While suspended CABs shall not continue to perform conformance assessment services for the affected scope of accreditation and represent them under the NELAC program. PJLA shall change the CAB's accreditation status from suspended to accredited when the CAB demonstrates that it complies with the relevant requirements. A suspended CAB shall not have to reapply for accreditation if the cause/causes for suspension are corrected within six months or before the end of the period of accreditation, whichever is longer. If the CAB fails to correct the causes of suspension within six months after the effective date of the suspension or by the end of the period of accreditation (whichever is longer), PJLA shall withdraw or reduce the CAB's accreditation and the CAB is required to reapply for accreditation. No CAB's accreditation shall be suspended, withdrawn or reduced without the right to due process as set forth by PJLA.

Suspension shall not exceed six months or the period of accreditation, whichever is longer. Subject to applicable laws, regulations and due process requirements, PJLA may suspend, withdraw or reduce a CAB's accreditation if the CAB fails to meet the standards for accreditation. The CAB shall retain accreditation for the scope of accreditation, where it continues to meet the requirements of the Standard.

4.9 PROFICIENCY TESTING (ACCREDITATION PROCESS)

PJLA requires all CABS to conform to EL-V2M2-2011 for proficiency testing requirement. These will be assessed and monitored by PJLA continually, including on-site assessments.



Accreditation Procedure

4.10 RECORD RETENTION (RECORDS)

PJLA currently retains records from three (3) to five (5) years minimum depending on the record. Records shall be maintained for longer periods based on specific state, federal or regulatory requirements.

4.11 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

PJLA will not delegate (whole or in part) the responsibility of CAB assessments to another organization.

4.12 PARTICIPATION & MAINTENANCE WITH THE TNI NELAP NON-GOVERNMENTAL PROGRAM

PJLA will participate with TNI for this program including attending on-going meetings and committees. PJLA will volunteer as necessary a delegated TNI NGAB evaluator to support this program.

4.13 CONFLICT OF INTEREST/CONFIDENTIALITY

PJLA has the appropriate conflict of interest and confidentiality agreements for all assessors and staff identified under PJLA's accreditation program. If at any time staff members of PJLA should impose any detrimental success to the program, then those staff members (employees or subcontracted employees) will be replaced with another member of equal and superior qualification.



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APPENDIX F: ACCREDITATION OF INSPECTION BODIES

1.0 SCOPE/PURPOSE

The accreditation of inspection bodies is performed by PJLA based on the operating criteria as outlined in ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies and ILAC-P15:06/2014 Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies.

This appendix includes information additional to the criteria as outlined in the main body of this document. (CABS) under the inspection program will be assessed to the all relevant requirements.

2.0 REFERENCES

- 2.1 ISO/IEC 17020:2012 –Conformity Assessment-requirements for the operation of various types of bodies performing inspection
- 2.2 ILAC-P15 “Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies.

3.0 DEFINITIONS

Inspection- Examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgement with general requirements

Inspection Body – A body that performs inspection, an organization can be an organization or part of an organization

Category A - An inspection body providing third party inspections

Category B- An inspection body providing first party inspections, second party inspections, or both, which forms a separate and identifiable part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and which supplies inspection services only to its parent organization (in-house inspection body)

Category C-An inspection body providing first party inspections, second party inspections, or both, which forms an identifiable but not necessarily a separate part of an organization involved in the design, manufacture, supply, installation, use or maintenance of the items it inspects and which supplies inspection services to its parent organization or to other parties, or to both.

CAB-A facility that is requesting accreditation to ISO/IEC 17020.

4.0 SUBSTANCE OF THE AGREEMENT



Accreditation Procedure

PJLA as an ILAC signatory for testing and calibration will perform assessments in accordance to ILAC criteria.

4.1 MANUAL/ORGANIZATION

PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011 and other national/international programs.

4.2 TRAINING AND QUALIFICATION

PJLA maintains a training, qualification and on-going continuing education program for assessors. A competency matrix is on file at PJLA Headquarters for assessors which indicate those areas of inspection which the assessor is qualified to perform on behalf of PJLA. Inspection assessors shall have at least 2 years of practical work experience performing inspections for one of the categories of inspection bodies (i.e. Category A, Category B or Category C). Additionally, they should be familiar with inspection requirements and methods, inspection and reporting processes and techniques, products and processes inspected, legislation and safety practices, sampling methods as applicable, and techniques used to assess professional judgment.

4.3 ASSESSMENTS AND DOCUMENTATION

PJLA will perform on-site assessments of (CABs) quality systems to include their general ISO/IEC 17020 requirements, and those outlined in PL1-PL-4 as applicable, along with PJLA Accreditation Symbol Procedure, SOP-3. Assessments will focus particularly on the Inspection Body's quality management system including impartiality requirements and technical requirements such as equipment, environmental conditions, and inspector qualifications including on-site monitoring, reporting and records. Assessments will consist of both on-site verification at client facilities and inspection processes being addressed at the main location of the Inspection Body. An inspection being conducted at client facilities may be sampled for the scope of accreditation. However, verification of former records of inspections will be verified at the fixed location. Aspects such as the following will be used for determining assessment planning:

- policy formulation;
- process and/or procedure development
- process of initial selection of inspectors
- as appropriate contract review
- planning conformity assessments
- review and approval of conformity assessments
- The extent to which inspectors are required to exercise professional judgment
- Total number of inspectors
- Frequency of each type of inspection
- Number of locations of the inspection body;



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- Past history of performance during (re)assessment;
- Personnel certification or other formal qualifications held by inspectors;
- The training system of the inspection body;
- Effectiveness of internal monitoring of inspectors;
- Organizational stability and risk awareness of the inspection body;
- Any statutory requirements

The choice of inspectors and inspections to be witnessed will take into account critical factors (e.g. new employees, the risks and the complexity of the inspection activity, physical capabilities of staff). PJLA internally document the analysis and/or rationale

used for sampling of inspectors to be witnessed to cover the scope of accreditation.

National legal requirements, regulations, standards or other relevant authority may stipulate levels of witnessing. Any such adjustments will be made explicitly in scope statements by reference to the relevant law, regulation, etc. as necessary.

Inspection Body's holding an ISO 9001 certification by an accredited (CAB) will be evaluated to avoid duplication wherever possible. However, all variances between the two standards will be assessed to ensure full compliance with ISO/IEC 17020:2012. In such cases, the (CAB) will be required to provide a copy of their current accredited certificate and latest assessment report for evaluation. PJLA will request CABs to submit annual reports and updated certificates on an annual basis at least 60-90 days prior to the scheduled assessment. Failure to submit this information will disqualify the (CAB) from any deviations from the assessment.

Assessments will be conducted on annual basis consisting of a full system assessment every two years with surveillance in between.

4.6 NOTIFICATION (CERTIFICATE PROCESS)

PJLA has an established executive committee to grant accreditation to Inspection Bodies. Executive Committee members will be selected based on their knowledge of the scope of accreditation. Upon the Executive Committee's final approval of the accreditation, a certificate will be created containing: the field of Inspection, Category of Inspection, Type of Inspection and Methods, Standards utilized for the Inspection.

4.7 RECORD RETENTION (RECORDS/COMPLAINTS)

PJLA currently retains records from three (3) to five (5) years (depending on the record), minimum.

4.8 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)

PJLA will not delegate (whole or in part) the responsibility of (CAB) assessments to another organization, which is not itself recognized under the ILAC MRA. This will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.



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4.9 SUBCONTRACTING OF (CAB) ACTIVITIES

All provisions of ISO/IEC 17020 regarding subcontracting will be enforced.

4.10 PARTICIPATION AND MAINTENANCE OF RECOGNITION

PJLA will participate in meetings with ILAC/APLAC as scheduled and announced, or at least once every year.



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APPENDIX G: ACCREDITATION OF LABORATORIES TESTING PRODUCTS SUBJECT TO THE FEDERAL COMMUNICATION COMMISSION CERTIFICATION AND DECLARATION OF CONFORMITY PROCEDURES

1.0 SCOPE/PURPOSE

The accreditation of CABs performing testing is done by PJLA based on the operating criteria as outlined in ISO/IEC 17011:2004 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.

This appendix includes information additional to the criteria as outlined in the main body of this document. Conformity Assessment Bodies (CABs) under the Federal Communication Commission (FCC) Office of Engineering and Technology (OET) program will be assessed to the all relevant requirements summarized in the document referenced in section 2.0 of this document.

PJLA will accept applications for FCC testing laboratories desiring ISO/IEC 17025:2005 within the United States or outside the United States where no MRA exists between a particular country and the United States for this program. Specific international laws and requirements will be evaluated prior to conducting any assessments outside of the United States.

2.0 REFERENCES

- 2.1 ISO/IEC 17011:2004 General requirements – General requirements for accreditation bodies accrediting conformity assessment bodies
- 2.2 ISO/IEC 17025:2005 General requirements for the competency of testing and calibration laboratories, 2nd ed.
- 2.3 FCC Office of Engineering and Technology Laboratory Division “Accredited Testing Laboratory Program Roles and Responsibilities”, June 16, 2016.
- 2.4 FCC Office of Engineering and Technology Laboratory Division “OET Procedures for the Recognition Laboratory Accreditation Bodies June 16, 2016.

3.0 DEFINITIONS

Accreditation Body (AB) - Authoritative body recognized by the FCC that performs accreditation. Accreditation is a third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. The accrediting bodies assessing testing laboratories for the Certification or Declaration of Conformity (DoC) must be recognized by the FCC and/or under a government to government Mutual Recognition Agreement (MRA).

Certification – a rigorous equipment authorization procedure typically applied to RF equipment employing new technologies, or complex or not well defined testing methods, or having a high potential for causing interference. Examples are: mobile phones, wireless networking equipment, mobile radio transmitters, wireless medical transmitting equipment, cordless telephones, etc. All certified equipment is listed by the FCC in a database containing the application for certification, test report and other supporting information.



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Declaration of Conformity (DoC) – A self approval process requiring a responsible party to use a FCC-recognized accredited test laboratory (CAB) to perform the measurements required to demonstrate compliance. The responsible party must include a compliance information statement that identifies the product and responsible party in the United States. (see 47 CFR 2.906 and 2.909).

Conformity Assessment Body (CAB) – A body that performs conformity assessment services. Testing laboratories and certification bodies are considered to be conformity assessment bodies.

Designating Authority (DA) – A body responsible for determining that the testing laboratory is competent and capable of performing testing within the scope of the designation.

Testing Laboratory – A CAB performing testing that is responsible to make a determination of the applicable test procedures and to properly test to those requirements. All testing for devices for certification or DoC is to be done by a recognized accredited testing laboratory. This includes EMC and radio parameter testing or other FCC technical requirements such as hearing aid compatibility, RF exposure testing, etc.

4.0 SUBSTANCE OF THE AGREEMENT

PJLA as an ILAC signatory for testing and calibration will perform assessments in accordance to ILAC criteria. In addition, PJLA will comply with the requirements of the FCC Office of Engineering and Technology (OET) accredited testing laboratory program and/or the NIST laboratory accreditation program to support the Asia Pacific Economic Cooperation (APEC) Mutual Recognition Agreement (MRA) for the Conformity Assessment of Telecommunications Equipment.

4.1 MANUAL/ORGANIZATION

PJLA maintains a quality manual and operating procedures and work instructions to document its quality system to comply with ISO/IEC 17011 and other national/international programs including the FCC Office of Engineering and Technology (OET) accredited testing laboratory program and/or the NIST laboratory accreditation program to support the Asia Pacific Economic Cooperation (APEC) Mutual Recognition Agreement (MRA) for the Conformity Assessment of Telecommunications Equipment.

4.2 TRAINING AND QUALIFICATION

PJLA maintains a training, qualification and on-going continuing education program for assessors. A competency matrix is on file at PJLA Headquarters for assessors which indicate those areas of testing and calibration which the assessor is qualified to perform on behalf of PJLA. The assessors for this program assessors shall have at least 2 years of practical work experience performing testing for electromagnetic compatibility, electromagnetic interference, radio, and telecommunications equipment. Additionally, they should be familiar with testing requirements, techniques, and methods; reporting;



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products and processes inspected; FCC rules and procedures, the OET Knowledge Data Base (KDB); safety practices; sampling methods as applicable, and techniques used to assess professional judgment.

4.3 TESTING LABORATORIES PROCEDURES AND SCOPES OF ACCREDITATION

PJLA will perform on-site assessments to include the general ISO/IEC 17025 requirements, and those outlined in PL1-PL-4 as applicable, along with PJLA Accreditation Symbol Procedure, SOP-3. Assessments will focus on the CAB's quality management system including impartiality requirements and technical requirements such as equipment, environmental conditions, proficiency testing, measurement uncertainty, reporting and technical qualifications. The assessment will cover the regulations and measurement procedures for EMC, radio, or telecommunication devices for a CAB performing tests in support of the FCC's Declaration of Conformity (DOC) and Certification requirements as summarized in Table A. Assessments will consist of both on-site verification at client facilities and testing activities being addressed at the main location of the CAB. Testing being conducted at client facilities or other locations may be sampled for the scope of accreditation. However, verification of former records of testing will be verified at the fixed location.

Table A provides a list of the scopes of accreditation for testing performed including test methods in support of the FCC DoC and Certification approval procedures. The testing laboratory is assessed to show that it is competent to perform testing using the applicable test methods for the scope of accreditation. The testing laboratory needs to have a working knowledge of the applicable KDB Publications at the time of the assessment. If the testing laboratory is being assessed and found competent for a scope in Table A that has a KDB publication identified in the test method column of Table A, then the KDB publication will be identified by version in the scope of accreditation provided to the FCC. If the testing laboratory is being assessed and is found competent for a scope that has a KDB publication identified in the supporting FCC guidance column of Table A, it will not be necessary to include the KDB Publication on the scope of accreditation.

A testing laboratory is not required to be assessed and recognized for all of the scopes identified in Table A. However, scopes identified in Table A may be limited to upper frequency ranges but will not otherwise be recognized as partial scopes by the FCC. The maximum assessed frequency for each scope is the highest measurement frequency that the testing laboratory is capable of performing measurements. The maximum frequency range capability of the testing laboratory for each scope of accreditation will be specified. Deviations from the test methods as permitted in the FCC rules and procedures will be accepted. Any test method limitations in the testing laboratory's capability to perform all of the tests indicated in the test method for a given scope will be identified (e.g., ANSI C63.10-2013 requires the use of the site validation requirements in CISPR 16-1-4:2010-04, however, the FCC rules allow for a transition period of July 13, 2018.)



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Radiated Emissions Test Facility

Antenna Calibration. Testing laboratories performing radiated emission measurements and NSA measurements, as required by the FCC rules, are required to use antennas calibrated in accordance with ANSI C63.5-2006.15

Site Validation Requirements. When using radiated emission test procedures that require the use of a validated test site (e.g., ANSI C63.4-2014 and ANSI C63.10-2013) the test site used shall meet the following site validation requirements

PJLA will retain a list of scopes based on Table A for each accredited test lab on the PJLA Website. Once the FCC Electronic Filing System is completed certificate information will be updated to include specifics as listed in Table A.

Accredited testing laboratories can meet the full scope requirements using multiple testing locations of the same company at different locations as long as the laboratory has demonstrated that each laboratory falls under the same quality management system and all reside within the same country.

Assessments for this program will include the completion of the FCC Accredited Test Laboratory Technical Assessment Evaluation checklist, which contains specific items to be covered in the technical assessment of the laboratory as to its competence in testing to FCC regulatory requirements contained in 47 CFR. The checklist is intended as a guide to provide a minimum of items to be covered in the technical assessment to ISO/IEC 17025 requirements. Technical assessors shall also use sound and appropriate engineering and other judgment in the assessment of the CAB. For initial accreditation assessments this checklist will be submitted to the FCC by PJLA. For reassessments a completed checklist with a statement indicating continued compliance will be submitted. Completed checklists will be made publicly available on the FCC website. Routine surveillances conducted in between initial and renewal assessments will also include an assessment of the laboratory scope. A checklist or portion of the checklist will be completed and submitted to the FCC as requested.

Assessments will be conducted on annual basis consisting of a full system assessment every two years with surveillance in between.

Radiated Emissions Test Facility

Test facilities used to make radiated emission measurements from 30 MHz to 1 GHz are required to meet the site validation requirements in ANSI C63.4-2014.

For radiated emissions 1 GHz to 40 GHz the test facility used can use either site validation option in 5.5 of ANSI C63.4-2014. On and after the transition date, July 13, 2018, the test facility is required to comply with the site validation requirements in CISPR 16-1-4:2010-04.

Validation of the acceptability criterion shall be confirmed no less than once every three years.



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Description of radiated emission test facility- A description of the measurement facilities used by the testing laboratory are required to be maintained in accordance with § 2.948(b).

Compliance Testing Experimental Radio Licenses. A testing laboratory located in the United States or territory of the United States that performs testing at an open area test site is required to have a valid compliance testing experimental radio license, per Subpart G of Part 5 of the rules

4.6 NOTIFICATION (CERTIFICATE PROCESS)

PJLA has an established executive committee to grant accreditation to CABs. Executive Committee members will be selected based on their knowledge of the scope of accreditation. Upon the Executive Committee's final approval of the accreditation, a certificate and scope will be created containing the information as specified in Appendix G, Section 4.3 and Table A of this document.

Under the FCC program, PJLA as the designated authority (DA) designates the CAB directly to the FCC. PJLA will provide the following information to the FCC for its review and recognition:

1. Name, location, mailing and contact information.
2. Designation number and FCC Registration Number (FRM)
3. ISO/IEC 17025:2005 certificate of Accreditation (or equivalent information), including the scope of accreditation with the FCC related test methods and supporting FCC guidance for the accredited test laboratory as indicated in Table A of this appendix.
4. FCC rule sections the accreditation applies to
5. The expiration date and period of accreditation
6. Completed Accredited Laboratory FCC Technical Assessment checklist and/or (for renewals) a statement of continued compliance.
7. A statement that the test laboratory complies with all provisions of the Accredited Testing Laboratory Program Rules and Responsibilities.

Upon this review, the FCC will notify PJLA as the DA regarding the decision regarding the request for recognition.

PJLA as the DA will submit the materials directly to the FCC, and not the CAB, through the use of the designated FCC database. For renewals, PJLA will update the FCC database expiration date.

4.7 RECORD RETENTION (RECORDS/COMPLAINTS)

PJLA currently retains records from three (3) to five (5) years (depending on the record), minimum.

4.8 DELEGATION (SUBCONTRACTING OF ASSESSMENT ACTIVITIES)



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PJLA will not delegate (whole or in part) the responsibility of (CAB) assessments to another organization, which is not itself recognized under the ILAC MRA, the FCC accreditation body recognition program or that does not have an MRA with the United States for this program. This will not extend to the assessors themselves, many/most of who are independent contractors. PJLA confidentiality and conflict of interest policies will be enforced.

4.9 SUBCONTRACTING OF (CAB) ACTIVITIES

All provisions of ISO/IEC 17025 regarding subcontracting will be enforced. When an FCC-recognized accredited testing laboratory uses external resources to perform testing, after July 12, 2017, it is required that such testing be performed by testing laboratories that have also been recognized by the Commission as accredited with the appropriate scope of accreditation.

4.10 PARTICIPATION AND MAINTENANCE OF RECOGNITION

PJLA will participate in meetings as required by the FCC and participate in forums to ensure updates to the program are being properly implemented. The FCC and/or NIST will be notified of routine peer evaluations and a schedule of assessments in order to witness CABs.



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TABLE A: TESTING LABORATORY SCOPES OF ACCREDITATION-
Scopes of Accreditation for testing performed in support of FCC DoC and
Certification approval procedures

Microwave frequencies as used in this part, this term refers to frequencies of 890 MHz and above

Scope	Test Method(s)	Supporting FCC Guidance
Unintentional Radiators (FCC Part 15, Subpart B)	<ul style="list-style-type: none"> ANSI C63.4-2014 	
Industrial, Scientific, and Medical Equipment (FCC Part 18) <ul style="list-style-type: none"> Consumer ISM equipment 	<ul style="list-style-type: none"> <u>FCC MP-5 (February 1986)</u> 	
Intentional Radiators (FCC Part 15 Subpart C)	<ul style="list-style-type: none"> ANSI C63.10-2013 	
UPCS (FCC Part 15, Subpart D) <ul style="list-style-type: none"> Unlicensed Personal Communication Systems devices 	<ul style="list-style-type: none"> ANSI C63.17-2013 	
U-NII without DFS Intentional Radiators (FCC Part 15, Subpart E) <ul style="list-style-type: none"> Unlicensed National Information Infrastructure Devices (U-NII without DFS) 	<ul style="list-style-type: none"> ANSI C63.10-2013 	<ul style="list-style-type: none"> <u>KDB Publication 789033</u>
U-NII with DFS Intentional Radiators (FCC Part 15 Subpart E) <ul style="list-style-type: none"> Unlicensed National Information Infrastructure U-NII) Devices with Dynamic Frequency Selection (DFS) 	<ul style="list-style-type: none"> FCC KDB Publication 905462 D02 UNII DFS Compliance Procedures New Rules v01 (April 8, 2016) 	
UWB Intentional Radiators (FCC Part 15, Subpart F) <ul style="list-style-type: none"> Ultra-wideband Operation 	<ul style="list-style-type: none"> ANSI C63.10-2013 	
BPL Intentional Radiators (FCC Part 15, Subpart G) <ul style="list-style-type: none"> Access Broadband Over Power Line (Access BPL) 	<ul style="list-style-type: none"> ANSI C63.10-2013 	
White Space Device Intentional Radiators (FCC Part 15, Subpart H) <ul style="list-style-type: none"> White Space Devices 	<ul style="list-style-type: none"> ANSI C63.10-2013 	
Commercial Mobile Services (FCC Licensed Radio Service Equipment) <ul style="list-style-type: none"> Part 22 (cellular) Part 24 Part 25 (non-microwave) Part 27 	<ul style="list-style-type: none"> ANSI/TIA-603-D TIA-102.CAAA-D 	<ul style="list-style-type: none"> <u>KDB Publication 971168</u>



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General Mobile Radio Services (FCC Licensed Radio Service Equipment)¹⁹ <ul style="list-style-type: none"> • Part 22 (non-cellular) • Part 90 (non-microwave) • Part 95 • Part 97 • Part 101 (non-microwave) 	<ul style="list-style-type: none"> • ANSI/TIA-603-D • TIA-102.CAAA-D 	
Citizens Broadband Radio Services (FCC Licensed Radio Service Equipment) <ul style="list-style-type: none"> • Part 96 	<ul style="list-style-type: none"> • ANSI/TIA-603-D • TIA-102.CAAA-D 	<ul style="list-style-type: none"> • KDB Publication 971168
Maritime and Aviation Radio Services (FCC Licensed Radio Service Equipment) <ul style="list-style-type: none"> • Part 80 • Part 87 	<ul style="list-style-type: none"> • ANSI/TIA-603-D 	
Microwave and Millimeter Bands Radio Services (FCC Licensed Radio Service Equipment) <ul style="list-style-type: none"> • Part 25 • Part 74 • Part 90 (90Y, 90Z, DSRC) • Part 101 	<ul style="list-style-type: none"> • ANSI/TIA-603-D • TIA-102.CAAA-D 	
Broadcast Radio Services (FCC Licensed Radio Service Equipment) <ul style="list-style-type: none"> • Part 73 • Part 74 (non-microwave) 	<ul style="list-style-type: none"> • ANSI/TIA-603-D • TIA-102.CAAA-D 	
RF Exposure <ul style="list-style-type: none"> • Devices subject to SAR requirements 	<ul style="list-style-type: none"> • IEEE Std 1528™-2013 	<ul style="list-style-type: none"> • KDB Publication 865664 • KDB Publication 447498
Hearing Aid Compatibility (Part 20) <ul style="list-style-type: none"> • HAC for Commercial mobile services 	<ul style="list-style-type: none"> • ANSI C63.19-2007; or • ANSI C63.19-2011 	
Signal Boosters (Part 20) <ul style="list-style-type: none"> • Wideband Consumer signal boosters • Provider-specific signal boosters • Industrial signal boosters 	<ul style="list-style-type: none"> • FCC KDB Publication 935210 D03 Signal Booster Measurements v04 (February 12, 2016) • FCC KDB Publication 935210 D04 Provider Specific Booster Measurements v02 (February 12, 2016) • FCC KDB Publication 935210 D05 Indus Booster Basic Meas v01r01 (February 12, 2016) 	



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PJLA offers third-party accreditation services to Conformity Assessment Bodies (i.e. Testing and/or Calibration Laboratories, Reference Material Producers, Field Sampling and Measurement Organizations and Inspection Bodies). This procedure outlines PJLA's accreditation process and criteria administered to conformity assessments bodies. **Note-PJLA offers several supplemental programs above ISO/IEC 17025. Additional supplemental procedures may be available for these programs and shall be applied in addition to this general accreditation procedure.**



Accreditation Procedure

1.0 INTRODUCTION

- 1.1 Perry Johnson Laboratory Accreditation, Inc. (PJLA) is a Michigan corporation wholly owned by Perry Lawrence Johnson ("Stockholder"). Mr. Johnson has no active management role in the operation of PJLA, and PJLA has no corporate relationship to Mr. Johnson's other business enterprises.
- 1.2 PJLA services include assessment and accreditation of conformity assessment body (CAB) systems to international, national, regulatory or governmental standards or program requirements.

2.0 SCOPE

- 2.1 This procedure covers the scope of the PJLA assessment and accreditation service. It conforms to ISO/IEC 17011: 2004 and other national and/or international standards as applicable. National, regulatory or government specific accreditation programs are outlined in appendices of this document. Accreditation criteria not covered in the appendices can be found in the body of this document. Note- In many cases, throughout this document, baseline ISO/IEC 17025:2005 program documents are referenced. Some of these documents belong to a series of documents for use in other accreditation programs (i.e. LF-1, LF-1elap, etc.).

3.0 DEFINITIONS

- 3.1 **Accreditation Body (PJLA):** Authoritative Body that performs accreditation.
- 3.2 **Accredited/Applicant Conformity Assessment Body (CAB):** A body that performs conformity assessment services that can be the object of accreditation.
- 3.3 **Accreditation Certificate of Approval:** A formal document or set of documents, stating that accreditation has been granted for the defined scope
- 3.4 **Assessment:** Process undertaken by an accreditation body to assess the competence of the (CAB) based on particular standard(s) and/or normative documents and for a defined scope of accreditation.
- 3.5 **Assessor:** Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a (CAB).
- 3.6 **Preliminary Assessment (Preassessment):** An informal assessment carried out by PJLA to assess a (CAB) prior to the Initial Accreditation Assessment. The objective of the preassessment is to identify system gaps so that corrective actions can be implemented prior to the formal Accreditation Assessment.



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- 3.7 **Accreditation/Reassessment:** Full System third-party attestation related to a (CAB) conveying formal demonstration of its competence to carry out specific conformity assessments tasks.
- 3.8 **Surveillance Assessment:** Set of activities, except reassessment, to monitor the continued fulfillment by an accredited (CAB) of requirements for accreditation.
- 3.9 **Accreditation Symbol:** A symbol issued by an accreditation body to be used by accredited (CAB) to indicate their accreditation status.
- 3.10 **Registry:** Listing of accredited (CABs).

4.0 REQUEST FOR ACCREDITATION

- 4.1 The applicant (CAB) initiates the Accreditation Process via a written or verbal request for information. In response, PJLA provides the applicant with a Client Profile/Questionnaire (LF-1). PJLA will also supply them with additional PJLA accreditation system documentation/information as necessary.
- 4.2 The applicant completes the (LF-1), which provides PJLA with the initial information required to commence the accreditation process. This document elicits from the applicant the following details, among others:
 - 4.2.1 contact name (address, etc.);
 - 4.2.2 description of testing/calibration/RMP/FSMO/Inspection performed, including a description of activities performed at the organization's facility, customer locations, and in-house calibrations performed as applicable;
 - 4.2.3 description of equipment used;
 - 4.2.4 description of methods used;
 - 4.2.5 description of premises of facility, number of employees, traveling employees and work shifts, and;
 - 4.2.6 status of existing system.
- 4.3 If the (LF-1) is not complete, it will be rejected and the (CAB) will be contacted for more detail. No quotation will be generated without having enough information to determine the appropriate amount of time to spend at the facility, including information in regards to the (CAB) structure and scope.
- 4.4 PJLA makes its services available to all (CABs) whose requests are concurrent with PJLA's scope of activity. In the event the applicant requests accreditation services in unfamiliar areas, PJLA will utilize a technical expert to assist with the quoting process including the determination of: allocation of assessment days,



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assessor competency, and committee competency needs. If the technical resources cannot be formulated, then PJLA will reject the request for quotation.

- 4.5 On the basis of the information furnished by the applicant, PJLA provides a quotation to cover the cost of the accreditation and subsequent surveillance visits. The required number of assessment man-days is determined by examining the number and types of activities being performed at fixed locations and at customer locations, number of sites and number of technicians residing within the (CAB). At no such time will an accreditation assessment be quoted for less than 1.0 day on-site and .50 day off-site. The quotation may also include additional services such as preliminary assessments and on-site training activities. Applicants are informed that quotations received are based on the information as detailed in the application and is subject to change if inadequate or incomplete information was provided.
- 4.6 Should the applicant wish to proceed with accreditation, the applicant then signs, and returns a copy of the Agreement for Services bearing an original signature. The receipt by PJLA of this document is taken as an instruction to proceed in accordance with the agreement for services and associated procedures. At this stage, the applicant also provides PJLA with the following:
 - 4.6.1 Written confirmation of preferred dates for the preassessment (if applicable) and accreditation assessment
 - 4.6.2 Payment of the first installment per the Agreement for Services
- 4.7 Once the agreement is finalized a proposed scope for the assessment will be created based on the information retrieved from the application. This template will be submitted to the (CAB) prior to their assessment to confirm their scope and submitted to the lead assessor for verification and finalization during the on-site assessment.
- 4.8 If the requirements for accreditation change at any time needing retroactive implementation, PJLA will ensure that the (CAB) is notified within a reasonable timeframe in order for the (CAB) to successfully complete implementation.
- 4.9 PJLA reserves the right to amend said Agreement for Services at any time if significant changes have occurred or unexpected circumstances take place with the applicant/accredited (CAB). **This includes, but is not limited to: relocation or modification of premises, ownership change or merger, personnel changes, equipment changes, changes in main policies or capability to perform the scope of accreditation. PJLA has the right to request an on-site assessment resulting from complaints where evidence of conformity is required. Additionally, follow-up visits may be required in order to confirm CAB's corrective action implementation when severe nonconformities are detected during an assessment. *It is the responsibility of the applicant/accredited (CAB) to inform PJLA of any significant changes that could impact their accreditation immediately.***



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5.0 ASSESSMENT CONFIRMATION

- 5.1 Once the agreement for service is finalized PJLA will contact the applicant (CAB) to confirm the scope of accreditation and details of the organization as provided on the application. The scope of assessment will be developed upon confirmation of the assessment. Any questions or comments derived from the development of the scope will be submitted to the (CAB) for clarification. During the same time the (CAB) will discuss arrangements for the assessments (assessors, dates and off-site premises where activities of their scope are being performed as applicable), to ensure adequate time and an adequate schedule can be developed to perform the assessment. No Assessor will be assigned or permitted to conduct any assessments where they have participated in more than two (2) preliminary assessments of the accreditation client or in any way has given PJLA the impression that a conflict of interest could occur between the assessor and the (CAB). Assessors or any members of the team will have signed agreements with PJLA to avoid such conflict of interests with (CABs). The (CAB) will be clearly communicated in regards to the names of the assessor(s) by PJLA. The (CAB) has the right to object to any members of the assessment team assigned. In cases where an assessor arrives on-site at the (CAB) and detects or is informed of a conflict of interest or a potential conflict of interest by them or by the CAB, then they should contact PJLA headquarters immediately to discuss the issue. If PJLA finds that the assessor is in a position that imposes a conflict of interest with the CAB, then a new assessor will be assigned or the assessment will be terminated. At no such time will PJLA allow the integrity and impartiality of an assessment to be jeopardized due to conflict of interests. PJLA appoints a qualified assessment team that includes members competent to assess the scope of the (CAB), including in-house calibration activities as applicable. If an assessment team cannot qualify for the scope of the (CAB) then a technical expert will be added to the team to provide the necessary technical expertise. Assessors and technical expertise will be evaluated against PJLA's Personnel Procedure (SOP-2) that includes guidelines for education, training and work experience requirements.
- 5.2 (CABs) will be provided with a readiness review checklist to ensure they are well prepared for their assessment. This includes them to provide any updates to their original application such as their scope, organizational changes, and their fulfillment of internal audits, management review and proficiency testing performance. Additionally, documents to start the initial documentation review are also requested to be submitted within a timeline of at least 30 days prior to the on-site assessment. During this stage if any feedback is provided to PJLA indicating that they are not prepared for their assessment then the (CAB) will be notified that their assessment is recommended to be postponed.
- 5.3 (CABs) will be required to sign all assessment confirmation forms prior to each assessment. Postponement or cancellation of assessments obligates the (CAB) to pay cancellation fees as specified in (LF-3), Agreement for Services.